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Intellectual Property and the Genetic *Dispositif* of Life

The Changing Role of Intellectual Property Law in Governing
Participation and Knowledge in the Bioeconomy

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International Relations

Submitted for the Degree of Doctor of Philosophy

University of Sussex, May 2015

Statement

I hereby declare that this thesis has not been and will not be, submitted in whole or in part to another University for the award of any other degree.

Signature:

Intellectual Property Rights and the Genetic *Dispositif* of Life –
The Changing Role of Intellectual Property Law in Governing
Participation and Knowledge in the Bioeconomy

Summary

This thesis analyses the problematic relation between intellectual property (IP) and genetic conceptions of life. The ‘gene patent’ has been controversial from its inception in the 1980s, and IP’s definition of genetic sequences continues to undergo surprising changes. Recent examples include the contested overturn of some forms of gene patents in the US Supreme Court *Myriad* judgement, and continuing international debates about access and benefit sharing arrangements in the newly established Nagoya Protocol. The *Myriad* case confronted an international neoliberal bioeconomy with new demands of patients, which increasingly define their understanding of health and well-being in molecular terms. This thesis argues that the issues surrounding the patenting of genetic sequences go beyond an already widely criticised ‘commodification’ of life, and points out that rather IP law is becoming a highly contested site in a wider problematization of the governing of life understood in molecular terms. Relying on an updated reading of Foucault’s concepts of governmentality and biopolitics, it argues that informational-genetic conceptions of life have opened up a new sphere of intensified biopolitics, based on a ‘genetic *dispositif*’ of knowledge and power. In its engagement with this *dispositif*, IP manages tensions between competing scientific knowledges about life, governs the participation of patients in medical research, and determines the rights of developing countries in an international bioeconomy. The analytical framework conceptualises these tensions as a confrontation with molecular biopower on three levels: in IP’s changing understanding of DNA, in IP’s relation to new ‘genetic’ subjects and medical research charities, and in challenges to IP’s exclusionary effects regarding the international sharing of benefits from research, and on demands for increased contributions to global health agendas. These challenges show how IP tactically contributes to the normalisation of knowledge, to the inclusion/exclusion of participation in the bioeconomy, and to the control of research agendas.

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Chapter I Introduction

“[F]or liberalism, the problem will be not a rejection of bio-political regulation but a way of managing it.” (Dean 2010, 121)

Recently, intellectual property (IP) law has once again become an unlikely site of ontological debate about the ‘essence’ of the genetic code. At the same time, the international organisation in charge of administering the international IP regime (the World Intellectual Property Organization, WIPO) is engaging in an ambitious development agenda and the renegotiation of international standards regarding the treatment of genetic resources and traditional knowledge. Patients and public-private-partnerships (PPPs) are using patents on genetic materials in order to facilitate easier access to genetic knowledge – instead of asserting monopoly rights that limit access and preclude a collaborative approach to research and development of new medicines. The World Health Organization (WHO) actively explores the potential of alternative mechanisms for the financing of research and development (R&D) of medicines addressing global health priorities that are being failed by the current approach. Furthermore, WIPO and WHO are collaborating with the World Trade Organization (WTO) in a trilateral initiative on this issue. The question of IP’s relation to life has become a key area of political contestation both within national and international legal frameworks, and recent IP strategies have begun to prioritise access and collaboration over monopolies and exclusion (Morin 2014; Williams 2012).

This thesis argues that these “paradoxes plaguing the intersection of the human body and intellectual property regimes in the present moment” (Waldby and Mitchell 2006, 136) cannot be explained through the prism of the “commodification” of life alone. Rather, analyses need to account for the emergence of a “new moral economy of R&D” (Lezaun and Montgomery 2015) and IP’s role within a “new somatic ethics” (N. Rose 2008a; 2007a), in which patients are incited to take active responsibility for their wellbeing. It argues that IP is becoming a central site that governs the increasing “problematization” of life (Foucault 1994, 114). Here, the predominant informational-genetic dispositif of life gives rise to intensifying tensions

between the patenting of genetic sequences and emerging practices of self-governing on the basis of genetic knowledge.

This thesis analyses the role of IP in confrontation with this shifting terrain of a politics of molecular life, and argues that it does more than provide commodities in the bioeconomy: IP governs participation and normalises knowledge, and thus acts as a “tactics” of government (Foucault 2000, 211), engaging “responsively” (Golder and Fitzpatrick 2009, 56) with challenges to these roles. IP’s relation to genetic conceptions of life thus goes beyond the “commodification” of life, and is better conceptualised as a confrontation with biopower, which can shed new light on the “paradoxes” at the intersection of genetic conceptions of life and IP law. The following chapters provide an in-depth analysis of IP’s contribution to the governing of life by managing tensions around truth discourses over life, the subject’s participation in the bioeconomy, and IP strategies for control over research agendas. This highlights two trajectories of challenges that are neglected in an overwhelming emphasis on commodification: the role of IP as a regime that excludes participation in the bioeconomy, and the role of IP in establishing control over a normalised version of knowledge over life.

1. Problematizing genetic conceptions of life

Over the course of the twentieth century, the discovery of the genetic code has fundamentally altered the conception of life – unearthing nothing less than the code containing “[t]he hereditary nature of every living organism” (Lewin 2004, 1). By now it has become commonplace to understand the genome of any organism as “a long sequence of nucleic acid that provides the *information* needed to construct the organism” (Ibid., emphasis in original). This conception of life contains a shift towards informational and genetic paradigms, which coalesced in the vastly successful rendition of biological life as determined by the *genetic code*: “the genome as an information system, a linguistic text written in DNA code” (Kay 2000, xv) has become the central research paradigm across the life sciences, and a central point of reference for understanding human existence in general. This fundamental knowledge over life has opened up a new sphere of politics surrounding “a quest for controlling information [...] frequently perceived as life’s logos” (Ibid.). This thesis argues that Intellectual Property Rights (IPRs) on human genetic materials have become a central site of struggle in this quest, providing and enabling control over this informational-

genetic rendition of life in the shape of gene patents and connected forms of intellectual property.

At the same time as the rise of the gene, intellectual property has “become one of the major issues of our global society” (Stiglitz 2008, 103), as a global system of enforceable temporary monopolies on knowledge was enshrined in the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS) as part of the WTO. This IP system became a key component for business strategies of pharmaceutical companies and other entities operating in the life sciences – including for example the “entrepreneurial university”, which actively uses IP for “rapid commercialization of basic research problems”, enabled for example in the US context by the *Bayh-Dole Act* (1980) (Rajan 2012, 2; Cooper 2008, 27). This commercialisation of research thrived especially at the intersection with the life sciences, where new “high-risk forms of investment” fuelled these “decidedly entrepreneurial, public-private alliances” (Cooper, *Ibid.*, 27). This thesis argues that in the new political economy of life, IPRs became a central concern – not only for the production of commodities for circulation in the economy, but also in a variety of roles asserting control over knowledge and over participation in this economy on the national and the international level. In fulfilling these roles, it is argued throughout this thesis, IPRs are increasingly contributing to the *governing* of life, and are negotiating tensions between economic priorities and a new sphere of politics surrounding the genetic-informational conception of life.

This new sphere of politics reaches far beyond the life science sector and its commercialised research, as it fundamentally re-shapes understandings of “humanness, illness and health” (Kay 2000, xv). The overwhelming influence of the informational-genetic paradigm continues to profoundly affect the individual’s relation to its own body, rendering the accessibility of genetic information an increasingly important marker of personhood. This thesis argues that understanding this fundamental impact on personhood can provide a new perspective on ongoing challenges to the exclusive commercial ownership of genetic sequences enabled by IPRs. Increasingly, patients and developing countries criticise IPRs as detrimental to their health and are actively challenging exclusive rights on testing kits such as for example the breast cancer test containing the BRCA-1 and 2 sequences in the recent *Myriad* case (*Assoc. for Molecular Pathology v. Myriad [2013]*). In a decision that came as a surprise to the biotech sector, this landmark case overturned some forms of

gene patents, arguing they contained a “product of nature” rather than an invention. The following chapters point out that this challenge to patentability was enabled by the overwhelming cultural and scientific success of the genetic code, and its claim of containing the essence of life. The Court however still maintained patentability of cDNA, arguing that it was “man-made”. This tenuous compromise shows IP’s precarious position in this new sphere of politics based on genetic knowledge, and at the same time highlights its continued importance to the industry.

The analysis of the confrontation between IPRs and life conducted in this thesis re-reads conflicts as an increasing “problematization” of genetic life for questions of governing (Foucault 1994, 114), and argues that in this context IPRs increasingly function as a “tactics” of government (Foucault 2000, 211), accommodating and resolving tensions between life and the economy. IP’s relation to genetic material is reinterpreted as a confrontation with biopower, in which IP law is being “governmentalized” and begins to negotiate tensions between different priorities of a new way of governing, instead of simply inscribing sovereign claims of power. This reading relies on Foucault’s notion of a new way of governing, or governmentality, which “set[s] up an economy at the level of the entire state, which means exercising [...] surveillance and control as attentive as that of the head of a family over his household and his goods” (Ibid., 207). This returns to a more original interpretation of ‘economy’, which emphasises the fostering of life and well-being as part of this new art of governing (Foucault 1978, 138) – and thus leads to the emergence of ‘biopower’.

This pastoral economy focused on the life of the population as an important point of reference: “the welfare of the population, the improvement of its condition, the increase of its wealth” (Ibid., 217), giving rise to particular biopolitical strategies. This new point of reference leads to a governmentalisation of the state apparatus, in which previously sovereign features of power increasingly act as tactics of economic governing. Sovereign aspects of power, such as law, thus become involved in the problematization of life for questions of governing, and contribute to the realisation of a pastoral yet economic fostering of life. This process of governmentalisation thus involves a range of adjustments and tensions for law (N. Rose and Valverde 2010, 543; Elbe 2009, 12), and renders it a central site that contributes to the governing of both life and the economy – accommodating two priorities that exist in some tension with each other (Dean 2010, 120). In an “analytics of power” (Dillon and Lobo-

Guerrero 2008, 272), this thesis studies IP's confrontation with the growing influence of a "genetic dispositif" on the level of conflicting truth discourses over life, in challenges to the control of genetic materials voiced by 'genetic' subjects, and in new strategies confronting IP's relation to life on the national and international level.

This analysis reveals that IPRs play a wider variety of roles in this political economy than previously suggested by critiques focusing on IP's function of the 'commodification' of life alone. At the intersection of life and the market, IPRs establish commodities for the trade of knowledge over life, but also play other important roles, for example privileging one vision of life over others and thus contributing to the normalisation of knowledge. Furthermore, they establish and maintain a dividing line of exclusion/ inclusion of participation in the area of IP policy making and in the life science economy, keeping challenges by patients and donors at bay. An analysis of debates on the global level shows the IP regime's function as a *regime of exclusion* in its starkest terms. The popular author Michael Crichton once argued "[y]ou, or someone you love, may die because of a gene patent that should never have been granted in the first place" (Crichton 2007) – on the international level, the detrimental effects of IP law are already a very painful and widespread truth (Godoy 2013). But even here, where the influence of donors and patients is still mostly excluded from participation in the development of IP policy, this division is coming under increasing pressure, as new strategies begin to contest this exclusion from within the core institutions of the IP apparatus.

This chapter briefly introduces this thesis' analytical perspective on the role(s) of IPRs in governing tensions between life and the economy in a neoliberal governmentality. After introducing the empirical scope of this analysis focusing on the practice of patenting information derived from human genetic material mostly by the pharmaceutical industry, the chapter then first outlines previous critiques of this practice, which deplore a growing "commodification" of life. This critique of the economic function of IPRs is then contrasted with the reading presented in this thesis that highlights the variety of roles played by IPRs confronted with genetic conceptions of life: the making of the commodity, the normalisation of knowledge, and the maintenance of the division between the economy and the sphere of influence of the responsible, self-actuarial subject (McNay 2009; Odysseos 2010; Novas and Rose 2000). This analysis will be carried out in three substantive chapters interpreting this as a confrontation with biopower (Rabinow and Rose 2006): the level of changing

truth discourses, emerging strategies for intervention challenging the existing system from a biopolitical perspective, and the modes of subjectification afforded to the individual under this system. In closing this chapter also briefly sets out the research methods employed in this project.

2. IP, the biotech sector, and patients – Contested relations

The issue of patents on ‘life’ has consistently been controversial and has been opposed vociferously by critics for example where it came to the patenting of plant life, seed material, and of human genetic sequences. Under US law, *Diamond v. Chakrabarty* (1980) (447 U.S. 303) established the patentability of micro-organisms, and *Moore v. Board of Regents* (1990) (51 Cal. 3d 120) settled the patentability of human genetic sequences in particular. However, this question has been far from uncontroversial ever since, and has very recently been addressed again directly by the US Supreme Court’s judgement on the *Myriad* case in a surprising turn away from previous legal practice regarding the definition of ‘life’ for the purposes of IP law (*Assoc. for Molecular Pathology v. Myriad* [2013] 569 U.S. 12-398). On the international level, the relation of IPRs to life has given rise to the *Doha Declaration on TRIPS and Public Health* (2001), which explicitly acknowledged the connection between IPRs and health for the first time, after growing discontent with the way in which issues that disproportionately affect the developing world were dealt with in the WTO’s framework (coming to a head for example in the “Battle of Seattle” in 1999; see also Stiglitz 2006, 76 ff.). The political force of confrontations between IPRs and life became obvious in instances such as the attempted lawsuit of over 40 major pharmaceutical companies against South Africa’s legislation seeking to bring down prices of HIV/AIDS medication – which was dropped in the face of world-wide press attention and NGO protests (Godoy 2013, 42 f.).

This thesis focuses on challenges to the use of IPRs mostly within the biotech/ life science sector of the pharmaceutical industry – thus mostly on patents, not questions of copyright. However, this is not an analysis of this industry, but of challenges to the use of IPRs coming from a variety of directions from outside and inside the industry (for example: patient groups, medical research charities, private-public-partnerships, indigenous communities). As the wider notions of well-being and responsible ‘healthy’ living are undergoing change due to the genetic conception of life, patients and individuals in general are increasingly demanding access to genetic

tests and seek to conduct themselves ‘responsibly’ according to their genetic condition. At the extreme end, this leads to people taking gene tests for BRCA 1 and 2 gene mutations, and then – as Angelina Jolie has famously done (Jolie 2013; Jolie Pitt 2015) – deciding to have mastectomies, hysterectomies, and further invasive surgery in order to minimise their ‘risk’. This creates a new subject: the “pre-symptomatic ill” (Wehling 2011, 234), which act on their body in novel ways in order to minimise risk and to prevent illness in the future – actions which coalesce into a new somatic ethics with specific rights and responsibilities (N. Rose 2008b; 2008a; Heath, Rapp, and Taussig 2004; Kerr 2003a; Kerr 2003b). These new “active patients” (N. Rose 2007b, 131; 2007a, 11) are also exerting pressure to increase the range of available treatments, or the access to tests and treatments, as the *Myriad* case shows: here, a wide range of patients, patient organisations, and doctors were challenging the exclusive practices around Myriad Genetics’ patents on the BRCA 1 and 2 test – which led to a startling partial overturn of previously recognised patenting practices of human genetic sequences.

The *Myriad* judgement and the debates around TRIPS and life highlight the potentially unpredictable consequences of the developing encounter of IPRs and a genetic view of life, and show that this transnational legal regime is negotiating between informational-genetic ‘truth’ of life and its continued patentability for the economy. This accommodation complicates the usual legitimisation of IPRs: they are usually portrayed as necessary measures for promoting research and development of new medicines, reimbursing the inventor for the inventive effort exerted in the development of medicines, and for the expenditure incurred in the development and trialling of this substance (Merges 2011; Stiglitz 2008). The inventive effort expended in the isolation of genetic sequences is however comparatively marginal, yet this classic legitimisation of IPRs is successfully used in a large-scale lobbying campaigns for example in favour of gene sequence patents in the EU Biotech Directive. Interestingly, this campaign at the European Parliament involved ‘active patients’ chanting the slogan “*No patents, no cure*” (see chapter V). This shows that the views of patients are becoming an important point of reference for legitimations of IPRs – especially as allegations of ‘astroturfing’ (i.e. the use of fake grassroots movements) emerged in the wake of the campaign, and continue to do so in context with later

associations between the industry and patients.¹ IP's exclusionary relation to this new influence of active patients is set out in particular in chapter V, while chapter VI shows how IPs maintain an even more exclusionary apparatus on the international level – which is challenged by a “new moral economy of R&D” (Lezaun and Montgomery 2015) within core international organisations.

3. The IP regime: connecting the national and international level

The analysis of IP's exclusionary function connects the international and the national level of IP law, with particular attention to the US IP system. This reflects the unique connection between the national and the international level contained in the current IP system. Here, the TRIPS agreement sets minimum standards on the international level, but their implementation depends on the particular national legal system – thus giving rise to national variations within an internationally guaranteed framework. Some larger regional bodies, such as the European Patent Office (EPO), harmonise rules within regions to some extent, but beyond that countries can form their own approaches. However, the TRIPS agreement created an internationally recognised standard of protection containing a very wide definition of patentable subject matter (i.e. any ‘invention’), and set out accepted exemptions to this. These definitions are very closely connected to the content given to them within the US patent system, as this section will briefly set out. Despite existing regional differences (see Rajan 2006 on India), the US approach thus remains the most relevant for an analysis of the parameters of international IP law contained in TRIPS – not least because of its very strong biotech sector. The history of the TRIPS agreement is clearly dominated by the influence of US industry and the IP systems of industrial countries (Sell 2003).

The TRIPS Agreement added to an international system of IP standards already contained in the World Intellectual Property Organisation (WIPO), which was established in 1967 as a United Nations agency administering the *Paris Convention for the Protection of Industrial Property of 1882*, and the *Berne Convention for the Protection of Literary and Artistic Work of 1886*, which constituted the first attempts

¹ For leaked documents allegedly proving the “mobilisation of an army of patient groups” by the pharmaceutical industry see Sample (2013). The European Patients' Forum responded with a strong denial of any “mobilisation” at the behest of industry (European Patients' Forum 2013), arguing rather that the disclosure of raw trial data is in the interest of all patient groups. While this debate is about the disclosure of data, it nonetheless shows that the input of patients groups is by now an important factor in the deliberations on such ‘technical’ arrangements of research conditions, and that patients groups have become very organised – and in the process their connection to industry is not always transparent.

to introduce an international dimension of IPRs (Matthews 2002, 10). These agreements set out minimum standards in this area and introduced the concept of ‘national treatment’, which is the concept of providing the same “national treatment for foreign works under domestic laws for patents, trademarks [...]” as for domestic works – but these treaties did not provide any effective mechanisms for enforcement of these standards (Ibid.). The TRIPS agreement incorporated most of the Paris and Berne conventions, but also tried to overcome their shortcomings, which were: “first, the absence of detailed rules on enforcement rights [...] and second, the absence of a binding and effective mechanism to settle disputes between states” (Ibid.). Intellectual Property Rights under this agreement are private rights, backed up by the principle of national treatment within courts, thus relying in their enforcement on public power as well.

The TRIPS agreement was substantially influenced by the private pressure group called the Intellectual Property Committee (IPC), consisting of chief executive officers of pharmaceutical, entertainment and software industries in the US, Europe and Japan (Sell 2003, 2; Tyfield 2008). They set out to strengthen existing protection measures and succeeded in gaining government support for a highly protectionist new agreement based on the already existing IP laws of industrialised countries, and thus globalised a previously national system reflecting the interests of industrialised states (Sell 2003, 2). Developing countries were then effectively coerced into accepting this regime as an obligatory part of the WTO, making the protection of IP a precondition for their own exports (Aoki 1998, 20). Correa argues that this “was also an expression of an aggressive action by the US industries to establish international rules that counter their declining competitive position in world markets” (Correa 2000, 5) – showing in how far this agreement was highly politicised from its inception (see also chapter VI for further discussion). National industrial interests were foundational to this international system, and are continuing to influence its development, as the US and a number of countries with an IP producing industry are pushing for even higher international standards of IP enforcement in ‘TRIPS Plus’ agreements such as the *Anti-Counterfeiting Trade Agreement* (ACTA), the *Transpacific Partnership* (TPP), and to some extent also in the current negotiations between the US and the EU as part of the *Transatlantic Trade and Investment Partnership* (TTIP) (Sell 2008; Abbott 2009; UNAIDS 2011; Geist 2010).

Foucault once argued in a lecture on the international dimension of the liberal system that “[t]he game is in Europe, but the stake is the world” (Foucault 2008, 56) – this thesis argues that this is particularly true in the case of the IP system, where the game is mostly in the US, while its ‘stake’ has become the world due to the global reach of TRIPS and the WTO. However, as chapter III demonstrates, in a neoliberal economy the IP regime has become even more crucial for the maintenance of the biotech’s industry’s interests – which rest on a functioning IP system for the raising of “speculative capital” (Cooper 2008). The international IP system thus is still very much determined by the expansive reach of US legislation and jurisdiction, tempered to some extent by the influence of other industrial countries or regional systems such as the EPO and to a lesser degree EU institutions. This thesis discusses contestations and debates occurring on the international level with a focus on the three most influential international organisations operating at the intersection of IP and life: the WTO, WIPO, and the World Health Organisation (WHO). Where relevant, it also considers tensions between the US and the EU approach (see chapter IV). In this, it focuses on an analysis of the IP system’s relation to genetic conceptions of life, which goes beyond the mere unidirectional ‘commodification’ of life, and creates increasing challenges for the IP system. In the negotiation of these challenges IP law becomes a central site for the governing of life.

4. Going beyond the Commodification Critique

The debate around IPRs and their relation to genetic conceptions of life has thus far centred on critiques of “biopiracy” (Shiva 1998; 2001) and of a “second enclosure of the commons” (Boyle 2003; 2008; May 2010). Both critiques highlight the “commodification” of life by means of the IP regime. The biopiracy argument challenges neo-colonial practices of capitalism, which are criticised for enhancing and exploiting international inequalities by turning the world’s biodiversity into commodities for the use in industrialised countries. The analogy of this situation to a “second enclosure” of the commons censures the monopolisation of goods belonging to the common wealth of the world, which impairs the free flow of knowledge and the potential for research. It is argued that this commodification and monopolisation of the ‘commons’ could potentially have equally detrimental effects to the first enclosure movement in 16th century England, which turned communally shared land into private

property, and thus created a rich class of landowners and a poor landless working class. The biopiracy critique looks more closely at the international distribution of the owners of IPRs, and highlights the inequality exploited by ‘bioprospecting’ projects, which transfer knowledge and human genetic materials from developing countries to rich IP holding industrial countries.

The focus on the ‘commodification’ of aspects of life presents a clear normative critique of this process’ detrimental effects on developing countries and the availability of knowledge for research and development. However, this critique places overwhelming emphasis on the economic determination of legal and social relations, in which IPRs are understood as a unidirectional mechanism enabling processes of commodification for exchange in the economy. This unilateral reading of IP’s role in the economy detracts from a deeper understanding of its conflicted and less unidirectional role in the normalisation of knowledge and in the regulation of participation of patients and developing countries within the bioeconomy. It also does not account for the variety of motivations for participation in such undertakings, not all of which are driven by economic concerns.

This thesis argues that an analysis of IP’s encounter with life needs to account for IP’s functions within a developing political sphere based on genetic conceptions of life. In contrast with the commodification critique’s unidirectional determination of IP’s role, Foucault’s notion of governmentality “understands the commodification of subjective experience not so much through ideas of passive consumerism, standardization and heteronomy, as through ideas of active differentiation, regulated self-responsibility and depoliticized autonomy” (McNay 2009, 62). Instead of looking at the homogenisation of society with reference to an alienating system of abstract value creation, Foucault’s concepts highlight how active processes of differentiation for instance contained in the notion of the “self as enterprise” give rise to a more resilient neoliberal system (Ibid., 63). The genetic conception of life here provides novel parameters for responsible conduct in a new “somatic ethics” (N. Rose 2008a). Importantly, these active processes of self-governing can both reinforce and also challenge the IP system, as in the case of PXE International’s use of patents on the genetic condition *pseudoxanthoma elasticum* (PXE) for the purpose of exerting control over research agendas without following commercial aims (see chapter V). IPRs on genetic conceptions of life are thus used in a less unidirectional way than the

notion of commodification suggests, and are rather becoming part of a diffuse net of power relations.

This perspective on the governing of life directs attention to the role of law in setting out the conditions on which the economic system operates – for example putting in place the rules necessary to guarantee a ‘free’ market. These conditions conduct the behaviour of individuals within this market, rather than just operating as restrictions, or punishments. Law thus is “productive” in this function, and becomes increasingly included in the “governing” of economic and social relations. Foucault’s concept of governmentality points to the central relevance of knowledge or ‘truth’ for the determination of appropriate conditions that “conduct the conduct” of individuals for example in the market (Foucault 2008, 186). These parameters also seek to enable a form of governing that intervenes as little as possible in the form of direct punishments or orders – heeding an “economic” calculus for determining an optimum amount of governmental intervention (Ibid., 19, 208, 319; N. Rose and Miller 2010). This economic calculus can however be challenged by emerging biopolitical strategies, which focus on fostering the life and wellbeing of populations on the basis of knowledge over life itself (Foucault 1978, 138).

This thesis argues that IPRs are increasingly embroiled in tensions between the operation of the market and the significance of genetic knowledge for the governing of life. At the intersection of knowledge and the market, the IP regime is doing more than merely creating commodities for exchange in the market: it elevates certain forms of knowledge over others, normalises an official canon of knowledge, enables specific forms of participation in the economy, and prevents others. In fulfilling these roles, the IP regime “governs” challenges arising from a genetic conception of life – which give rise to a particular politics of life. This analysis certainly does not mean to suggest that IPRs do no longer produce commodities for the economy, or that the entire apparatus of IPRs is undergoing a radical change, but rather seeks to trace an emerging engagement with a political sphere of life that can pose significant challenges to the IP regime on the international and the national level.

5. Conceptualising IP's encounter with life as giving rise to a 'governmentalisation of law'

"We can say that there was a juridification of the world which should be thought of in terms of the organization of a market." (Foucault 2008: 56)

The analysis of the political sphere based on genetic conceptions of life in the following chapters relies on an understanding of a new way of governing, or *governmentality*, derived from the writings of Michel Foucault and re-read in the context of a molecularised conception of life and a neoliberal economy with the aid of the work of Rabinow and Rose (2006), Rose (2007b; 2008a), Dean (2010), Elbe (2009), Dillon and Reid (2009), and Dillon and Lobo-Guerrero (2009). This new way of governing increasingly engaged with the biopolitical question of furthering the life and health of the population, for example through improvements of hygiene standards and better urban development (Foucault 2007, 18). In this way, the governing of life on the basis of knowledge over life increasingly became a central question or "problematization" for governmentality, which requires constant adjustments (Foucault 1994, 114). This thesis argues that IP's problematic treatment of human genetic materials shows that the question of governing life has become even more acute with a turn towards informational-genetic conceptions of life, which gave rise to large-scale bodies of statistical knowledge over the life of populations, combined with individualised accounts of health and future risks. Neoliberal economic forms of highly speculative investment in the life science/ biotech sector further intensified this problem (Cooper 2008). This thesis points out that economic law became crucial to speculative investments, which relied on IP as a security. As a result of these intensifications, IPRs became central to a specific part of the economy, which however also became increasingly involved in the question of defining and knowing life for the purpose of governing appropriately.

Foucault argues that the question of governing appropriately gave rise to a new "economic" way of governing indirectly, without overt sovereign intervention (Foucault 2000, 207; 2008, 19). In his work on governmentality, Foucault analyses the liberal preference for governing as little as possible by means of direct intervention, which rather operates through normalised parameters ensuring the realisation of aims by "government at a distance" (Miller and Rose 2008, 33 and 60).

Within this form of governing, different kinds of power “do not stand on an equal footing. Schematically, it is the newer, governmental economy of power that dominates” (Elbe 2009, 70). Dean highlights the potential for contradiction in the relation between biopolitical strategies focusing on the promotion of the life of the population and the economic calculus of governmentality: biopolitical strategies “challenge” the governmental system, while the economic calculus “manages” this challenge by imposing an economic “critique” on biopolitical power exercises (Dean 2010, 120).

This reading of governmentality’s central tension between life and the economy can clarify the role of law within concepts of governmentality, which is one of the central contributions of this thesis. Law as a meaningful area of study has been sidelined in most Foucauldian analyses – due to the fact that Foucault’s statements on the study and relevance of law were often dismissive and at times contradictory. It is argued here that this previously marginalised area of analysis needs to be resurrected and re-inserted into accounts of the modes of governing under governmentality, where law continues to play a role in the management of the problematization of life. Foucault noted that the turn towards biopolitical priorities entailed a “real inflation of the juridico-legal code” (Foucault 2007, 7). Instead of a disappearance of law, this turn can be understood as bringing about a “governmentalisation” of law (N. Rose and Valverde 2010, 543; Elbe 2009, 12). Here, the role of law changes, and is increasingly operating as a “norm” promoting responsible behaviour (Ewald 2010, 146; N. Rose and Valverde 2010, 546).

This understanding of the governmentalisation of law, however, needs to be further refined. Foucault also mentioned “a juridification of the world which should be thought of in terms of the organization of a market” (Foucault 2008, 56) – which points to law’s importance as a mechanism guaranteeing the implementation of governmentality’s core economic priorities. Golder and Fitzpatrick emphasize that the “governmentalisation” of law not only entails an increasingly normative function, but also that law “[engages] responsively with exteriority, with an outside made up of resistances and transgressions that assume a constituent role in law’s very formation” (Golder and Fitzpatrick 2009, 56). It is argued here that in this responsive way, law begins to contribute to both the governing of life and the organisation of the market, and becomes instrumental in the resolution of tensions created by the increasing problematization of life. In fulfilling this governmental function, law becomes what

this thesis understands as a “tactics” of government (Foucault 2000, 211; Odysseos 2010; Sokhi-Bulley 2013).

This transformation of the function of law can be observed in the IP regime’s complex relation to genetic conceptions of life. IPRs stand between the interests of the private and the public sector, enable the control and the normalisation of knowledge, and confer “power effects” (Foucault 1997, 180) on the holder of temporary knowledge monopolies. They fulfil an important role in the market – but are also increasingly fulfilling other aims, as shown in *Myriad*’s surprising turn away from some forms of patentability, and the use of IPRs by patients for aims that are not primarily economic, but rather concerned with directing research agendas. In these instances, control over a normalised version of knowledge and control over the use of genetic information are becoming more important “power effects” conferred by IP. As knowledge becomes central for governing according to “the nature of things” (Foucault 2008, 19), control over this knowledge becomes more than an economic concern.

In the ensuing tensions between the promotion of life and the guarantee of a working market, IPRs are functioning as more than an economic tool: they contribute tactically to the management of the ‘problematization’ of life. On the basis of ongoing contestations of IP’s treatment of genetic materials, this thesis explores the roles IPRs play in the management of the problematization of life, and the way in which this management destabilises assumptions on which IPRs are founded, such as the inventive step, and IP’s traditional legitimization as an economic incentive for research and development. Challenges arising from the encounter with life will be analysed on three levels, structured according to the constituent elements of biopower – truth, the subject, and exercises of power in the name of life (Rabinow and Rose 2006, 212). One chapter focuses on IP’s conflicted relation to knowledge over life (chapter IV), another on challenges to IP’s exclusivity posed by new modes of subjectification based on genetic conceptions of life (chapter V), and the last one analyses specific emerging strategies challenging IP’s exclusivity on the international level (chapter VI).²

² This chapter also engages with the problem of transposing Foucauldian ideas to the analysis of international relations, as debated between Kiersey, Weidner & Rosenow (2010) and Chandler (2010).

6. Revealing IP's role(s) in the governing of life

Three substantive chapters reveal different roles of IP in its function as a tactics of government, in which they normalise knowledges, impose a dividing line of exclusion/ inclusion of participation in the area of IP policy making and in the life science economy, and exert control over the further use of information derived from human genetic materials. The exercise of control over research and the exclusion of participation are most apparent on the international level, where IP excludes large parts of the world's population from participation in the direction of research. But in the core international organisations of IP and health, strategies in the name of life are challenging the IP system's exclusionary focus on the interests of patent holders at the expense of donor and patient communities around the world. Reports such as the Consultative Experts Working Group's (CEWG) report on *Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination* (CEWG 2012a) even begin exploring alternatives that could replace the existing IP system – on the basis of finding a 'market failure' of traditional mechanisms for the improvement of public health within developing countries. This "new moral economy of R&D" (Lezaun and Montgomery 2015) highlights the emergence of a new ethics within the international IP regime, and the IP regime's tactical management of challenges arising from this.

On the national level, the IP system's complete division between donors and IP derived from donation is well-established since *Moore v. Board of Regents* (1990), but a wider variety of strategies are challenging this status. The *Myriad* case shows that patients and doctors seek to minimise the exclusionary effects of the IP system, challenging the way in which IP can prevent access to genetic testing and to improved treatments. Also, patient groups at times become owners of IP to their own genetic condition in order to exert control over the research agenda in this area, as the case of *PXE International* and the strategic use of IP by medical research charities show (see chapter V). Here, IP is no longer used for primarily economic reasons, but rather in order to promote certain priorities based on the genetic condition of the patent holders – which are thus acting as "active patients" in Rose's sense: "actively choosing, and using medicine, biosciences, pharmaceuticals and 'alternative medicine' in order [*sic*] maximize and enhance their own vitality, demanding information from their doctors, expecting successful therapies, and liable to complain or even go to law if they are disappointed" (N. Rose 2007a, 11).

A closer look at the challenge posed by the entrepreneurial, self-actualising subject within this “vitalisation” (Dillon and Reid 2009, 21) of the economic role of IP shows that IPRs’ exclusionary effects play a role in the management of these new modes of subjectification. An analysis of the use of IPRs by biobanks and personal genomics businesses shows that IPRs operate as a regime of exclusion, demarcating the area of influence of individuals (donors/patients/customers) from that of experts and business. Here, the sphere of participation by individuals is structured as one of mostly donors or customers, which are involved in informed consent procedures and have the option of receiving instruction by an expert based on the results of their gene scan. These instructions can give rise to new norms of conduct, while the sphere of further economic and scientific use derived from this information remains closed off from participation. IP transfers control over the use of this information to the business, while the donor is only involved in a yes/no decision of consent to the general use of their data. IP is thus tactically maintaining the function of the economic use of information derived from genetic materials, keeping the influence of the active patient within bounds – and contributing to tipping the balance between individual rights and responsibilities within a new “somatic ethics” firmly towards responsibilities.

IPRs also contribute to a normalisation of knowledge (or ‘truth’) over life by rewarding specific types of research while side-lining other scientific paradigms. IP jurisdiction shows how its recognised understanding of the genetic sequence undergoes change from a ‘special’ chemical molecule to an informational entity, bringing about changes in the patentability of genetic sequences in the process. These changes are actually complicating the economic role of IPRs, which is why this thesis argues that they have to be understood as a concession to the central influence of the genetic view of life – here thought of as an influential ‘genetic *dispositif*’. This *dispositif* of the genetic code is based on valuable information on the life of the population and the individual, which makes it central to questions of the governing of life. Owning and controlling this information by means of IP directly involves this field of law into the definition of this life for the purpose of governing. Under this influence, it is argued here, IP jurisdiction can no longer maintain its understanding of genetic sequences as primarily chemical molecules – even if this would be more conducive for their commodification as information as such is not patentable.

By defining genetic sequences as essentially genetic-informational entities, IP jurisdiction contributes to the further normalisation of this relatively calculable and contains a ‘predictable’ conception of life. This decision shows how IP also plays a role in managing knowledge, as it privileges a conception of life that does not reflect current developments in scientific understandings. A turn away from the centrality of the genetic code is taking place in the field of the life sciences, moving instead towards accounts emphasising complexity and interaction with the environment (Carey 2012; Lewontin 2000; Landecker 2011). Interestingly, IP’s deliberations on the ‘truth’ of life have neither acknowledged nor discussed these fields of research, which date back to the foundational time of molecular biology. Francis Crick’s “central dogma” of the unidirectional mechanism of “DNA makes RNA makes protein makes us” marginalised other conceptions of life for most of the twentieth century (Crick 1970; the term “dogma” proved controversial, see Crick 1990, 109; H. Rose and Rose 2012, 31). The recent resurgence of an emphasis on environmental and systemic factors in epigenetics and systems biology produces more complex and less unidirectional accounts of molecular processes – which are less easily rendered in a form that could be patented (Calvert 2008) and also would be more difficult to interpret for the purposes of governing. Complexity thus endangers both the governing of life and the economic use derived from genetic information, which makes IP’s definition of genetic sequences as discrete informational objects a tactical production of certainty.

7. Core Contributions – IP’s role as a tactics for governing

The growing number of cases in which IPRs are used not for primarily economic purposes shows that in their encounter with genetic conceptions of life, IPRs are beginning to act as more than merely economic tools for appropriation. Instead of merely commodifying life, IPRs also become an important site at which the increasing problematization of life for governing gives rise to tensions between economic priorities and the definition of genetic conceptions of life, new modes of subjectification formed with reference to genetic knowledge, and specific interventions made in the name of life. By analysing these tensions in a frame of reference that is not entirely determined by economic relations, this thesis goes beyond previous critiques of IP’s role in the increasing ‘commodification’ of life and

contributes to the field of critical legal studies, and furthers especially the field of Foucauldian legal scholarship by studying a particularly underexplored area of law. IP's location at the intersection of knowledge and the market makes this an especially interesting field of law, which governs for the market – but is also challenged by a focus on the governing of life.

This thesis carries out an analysis of IP's role in managing challenges emerging from a political sphere based on genetic conceptions of life, or an increasing 'problematization' of molecular life, as Foucault might have put it (1994, 114). In contrast to previous critiques of IP's commodification of life, this thesis develops an analytical framework that traces the constituent elements of biopower as a "configuration of knowledge, power and subjectivity" (Rabinow and Rose 2006, 197 and 212). In this way, it develops an "analytics of power", which seeks to "[detail] the operational logics, forces and dynamics at play in a specific configuration of power relations" (Dillon and Lobo-Guerrero 2008, 272). This framework focuses the analysis on the problem of governing life within widening circuits of economic exchange. In analysing these different levels of change within an increasing emphasis on the governing of life, this framework can reveal the detailed processes through which governmental rationalities evolve. It furthermore allows for a reassessment of the role of law within Foucault's thought, and emphasises its foundational role for the implementation of conditions that encourage desirable behaviour and put in place the parameters within which the neoliberal 'free' market operates. This type of analysis contributes to the literature in governmentality studies, placing the previously neglected study of law firmly back into the remit of such studies.

Furthermore, this thesis also highlights the relevance of Foucault's concepts for studying a legal regime with a distinct international dimension, especially in the discipline of International Relations (Rosenow 2009; Kiersey 2009; Dillon and Reid 2009; Dillon and Lobo-Guerrero 2009). The IP regime connects the national and international level of law in a unique yet very powerful way, enshrining the IP systems of specific industrialised nations in an internationally enforceable treaty. As the later chapters show (V and VI), this IP system is challenged by genetic conceptions of life in different ways on the national and the international level, but the international reach of the IP system and the global sourcing of genetic materials for research makes this a very particular "new political economy of vitality", in which "transnational flows of knowledge, cells, tissues and intellectual property are coupled

with local intensifications and regulated by supranational institutions” (Rabinow and Rose 2006, 215). This transnational political economy faces relatively organised challenges in certain local intensifications such as the US, but still excludes most forms of participation by donor communities on the international level. However, a study of the debates within the supranational institutions shows how a political sector is forming around IP and global health, going back to the Doha Declaration on TRIPS and Public Health (WTO 2001). IP’s relation to donor communities in genetic resources is mostly debated in the field of plant and animal materials, but the interventions made in this field and within a wider evaluation of IP’s relation to health show that IP’s legitimacy is beginning to be fundamentally challenged in arguments about ‘market failure’ and through the use of human rights.

The analysis of the particular problematization of life in its genetic-informational form also adds further to the literature on the biopolitics of life “itself” (N. Rose 2007b, amongst others). This thesis revisits Foucault’s concepts based on 18th/19th century knowledge of body and argues that the genetic code’s connection between knowledge on the level of populations and on the level of the individual brought about an intensified influence of this type of knowledge over life, termed here the ‘*genetic dispositif*’. This does not only influence scientific research paradigms, but also deeply affects individual processes of identity formation and self-governing, giving rise to new molecular points of reference for conduct and enabling medical manipulation of the body’s basic constitutional processes (see for example debate on “genome editing” on human embryos, “Genome Editing: CRISPR Controls Gene Expression” 2015; Hilton et al. 2015; Liang et al. 2015; Sample 2015). The informational turn of genetic research made this even more effective, giving rise to new forms of technology and also to knowledge that can more easily be transferred into other scientific sectors, and into governmental and economic decision-making procedures. The neoliberal economy’s highly speculative investments in start-up companies founded on these forms of knowledge (Cooper 2008) further intensified the significance of the genetic conception of life, and thus posed an even stronger problematization of life for governing. At this intensifying intersection of knowledge and the economy, this thesis argues that IPs rapidly came under pressure to act as more than an economic tools and rather began to contribute to the governing of life as well.

8. Research Design

The research conducted for this thesis evaluated a wide variety of official publications from international organisations and legal documents including judgements, statutes, and supporting materials. Due to the highly interdisciplinary research focus of this project, I had to familiarise myself with research output and findings across several disciplines (Intellectual Property Law, International law, International Relations, Anthropology, Life Sciences). Further to this, I conducted a number of semi-structured anonymised elite interviews with key informants in the field of IP and molecular technology in London, Frankfurt, Munich and Geneva for the purpose of gathering information and grasping the complexity of debates that are carried out across various institutions and within the industry. Especially a week of intensive fieldwork in Geneva produced valuable insights into current debates in the three main international organisations operating at the intersection of IP and health: the WTO, WIPO, and the WHO. Key informant interviews were conducted with leading IP experts within the WTO, a leading representative of WIPO's negotiations on IP, genetic resources, and traditional knowledge, and a legal expert concerned with the WHO Consultative Expert Working Group's report on 'Strengthening Global Financing and Cooperation' (CEWG 2012a). A representative of the European Patent Office and a member of the UK's Intellectual Property Office were also interviewed.

Outside of the main international and national organisation, interviews were conducted with a range of non-governmental organisations (NGOs) in Geneva and in London. Interviews with an IP expert from *FIND Diagnostics*, with a representative of the *Medicines Patent Pool*, and with an IP expert from the *International Centre for Trade and Sustainable Development* (ICTSD) gave valuable insights into the increasing relevance of Public-Private Partnerships (PPPs) actively employing specific IP strategies in defined geographical contexts and with focus on particular illnesses such as AIDS and Tuberculosis. A leading expert from *Genetic Alliance UK* was interviewed on the topic of the increasing influence of patients' groups and their interests in genetic information. Several independent researchers were consulted in this field as well.

It proved more difficult to gain access to industry experts from within the pharmaceutical industry. Some of the interviewees had formerly been employed by large pharmaceutical companies. Beyond that, one interview was conducted with an IP expert representing the IP department of a medium-sized German pharmaceutical

company. Also, an IP lawyer specialising in the life sciences gave highly interesting professional insights into the developing political sphere of IP management rules, giving incentives for certain types of research on neglected or orphan diseases. These rules are a more elusive part of the sphere of IP law, however, they concern procedures guaranteeing data exclusivity and assigning exclusive market approval for example for medicines against orphan diseases (see chapter VI). A senior university researcher in the field of the life sciences was also interviewed on the increasing relevance of IP for their research.

All interviewees were very aware of the politically charged current discourse around ‘TRIPS Plus’ negotiations and the critical stance towards IP’s relation to life and health, especially in developing countries. This became very obvious in interviews with the industry, and with high-level representatives of WTO, WHO, and WIPO, which were at the time actively engaged in publishing the trilateral study on *‘Promoting Access and Medical Innovation: Intersections between Public Health, Intellectual Property and Trade’* (WHO, WIPO, and WTO 2013) – and very keen to avoid controversy or contradiction. It was difficult to get access to these representatives, and the interviews themselves were challenging as well. Virtually all interviewees insisted on anonymity, and most were reluctant to sign release forms for the content of the interviews. The interviews were semi-structured around questions tailored to the individual’s specialist position, aiming to gather information on the treatment of human genetic materials by the IP regime, and on ongoing debates within the respective organisation on this topic. I hoped to get an insight into several contested issues – such as the Convention on Biological Diversity’s unresolved relation to TRIPS (WTO 2015a) – but found that most interviewees were only comfortable talking about their current initiatives. While that somewhat broadened the scope of the interviews, it nonetheless reflected the complex, fractured terrain of the intersection of IP and life, clearly demonstrated the sensitivity of the debates, and showed how much is at stake in this confrontation.

9. Outline of Thesis

The following chapters first set out previous critiques of the ‘commodification’ of life, and then argue that tensions between molecular conceptions of life and the IP regime can be better grasped using an analytical framework that does not presuppose

the fundamental economic determination of social exchanges. Examples of the use of IPRs for non-commercial aims by charities confound expectations of unidirectional exploitation through commodification, giving rise to, as Waldby & Mitchell put it, “paradoxes plaguing the intersection of the human body and intellectual property regimes in the present moment” (2006, 136). The following chapters argue that the notion of commodification cannot adequately account for these paradoxes, but that more is at stake in these cases: the confrontation of the IP regime with a politics based on genetic conceptions of life. Foucault’s concepts of governmentality and biopower rely on an analysis of foundational conditions that give rise to economic relations, but also point to the governing of tensions emerging in an increasing problematization of life. Interrogating IP’s confrontation with elements of a new political sphere of life – truth, the role of the subject, and power – directs the focus onto tensions between knowledge and the economy without viewing them exclusively through the prism of capitalist market relations. This emphasises the influence of a ‘genetic dispositif’ in the creation of knowledge and the creation of economic value, which however also gives rise to challenges to the economic use of this knowledge.

The second chapter reviews the existing critical literature on IP’s treatment of human genetic materials, and also evaluates literature analysing the political dimension of the life science/ biotech sector without specific reference to IP. In this, it finds that critiques of IP mostly focus on its role in the ‘commodification of life’, either as an instance of “biopiracy” (amongst others: Shiva 1998; 2001) or as a new “enclosure of the commons” (Boyle 2003; 2008; May 2010). The chapter argues that this critique focuses the debate on economic circuits of exchange and mechanisms of value attribution, without taking into account the wider social relevance of genetic knowledge beyond the life sciences. Some of the literature contrasts capitalist economic relations with the concept of the gift relationship in order to capture these interactions. However, this thesis argues that new incentives for the use of IP emerge as part of a political sphere based on genetic conceptions of life, which need to be analysed from a perspective that does not conceive of this sphere as predominantly and unilaterally determined by economic value. The chapter traces a beginning turn towards an analysis of “life as a productive force” (Yoxen 1981) within the emerging sphere of the “politics of life itself” (Franklin 2000; N. Rose 2007b), as studies begin to employ the Foucauldian concepts of biopolitics and governmentality to capture

social and power relations from a different perspective. However, the specific role of IPRs has not been studied by any of these scholars in depth.

The third chapter then introduces this thesis' analytical framework, which enables a more complex reading of IP's role in the encounter with genetic conceptions of life on the level of truth, the subject, and exercises of power (Rabinow and Rose 2006). Relying on Foucault's concepts of governmentality and biopolitics, this analysis traces the historical emergence of a new sphere of politics centred on the governing of life. Instead of directly enforcing the priorities of a sovereign, this form of governing puts into place conditions and parameters that guide conduct towards desirable outcomes. This leads to an incremental change in predominantly sovereign areas of governing, such as law, which are increasingly involved in the promotion of new priorities of governing such as the improvement of life. The chapter argues that these processes of change and resulting tensions have been intensified through the molecularisation of life and the increasing financialisation of life in the bioeconomy. In these intensified dynamics between knowledge and the economy, the IP regime is emerging as a central site of contestation – and is increasingly operating as a “tactics” of government (Foucault 2000, 211; Odysseos 2010; Sokhi-Bulley 2013) in order to resolve tensions.

This reading of IP law as a tactics of government further refines Foucault's position on the role of law in a governmental system. In a departure from some other interpretations of the relevance of law for Foucault's work, the chapter argues that law is central to the development of the “economic-juridical order” (Foucault 2008, 163) setting up the “rules of the game” (Ibid., 173) underlying a neoliberal economy. However, as law becomes involved in the promotion of governmental priorities, it also becomes “responsive” (Golder and Fitzpatrick 2009, 56 and 71) to challenges and resistance. This responsive dimension encapsulates the tactical operation of law, in which it negotiates or manages the potentially conflicting priorities of governing for the market and also promoting life and well-being. IPRs thus undoubtedly govern *for* the market by setting up a regime of ownership, which is also extended to genetic knowledge of life. However, IP also responds tactically to increasing pressures generated by the genetic code's pervasive societal influence and increasing relevance for questions of governing. This code integrates knowledge of the individual body with that of the population, and gives rise not only to new forms of medical

knowledge, but also to a new system of truth over life that conducts individuals' choices.

Guided by Rabinow and Rose's understanding of the elements of biopower (2006), the fourth chapter begins an in-depth analysis of the changing role of IPRs towards a tactics of governing by analysing its confrontation with different truth discourses on 'life'. As the recent *Myriad* judgement shows, this relation to truth over life is far from straightforward. The chapter first sets out the context of the surprising overturn of patentability of some genetic materials, and then argues that these changes cannot adequately be explained from a 'commodification' perspective alone. Rather, a turn towards a genetic-informational conception of life limited the patentability of isolated genetic sequences. However, the judgement still maintained patentability of other types of sequences (such as cDNA), thus can be seen as governing for the market as well – especially considering IP's continuing preference for a relatively defined genetic-informational conception of life over more complex, interactional interpretations of existence. In this sense, IPRs continue to normalise a particular conception of life that is conducive to governing the conduct of individuals and populations. In elevating this conception over other forms of knowledge, however, the patentability criteria of the IP regime are being pushed to their limits.

The fifth chapter then explores tensions between the subjectivities envisaged by the IP regime, and emerging modes of subjectification based on a genetic conception of life. Some 'genetic' subjects are contesting the IP regimes' exclusionary effects, while others are actively using IPRs for a new purpose, prioritising the furtherance of life and health of patients. These modes of subjectification are incited by "ideas of active differentiation, regulated self-responsibility and depoliticized autonomy" (McNay 2009, 62), following a new "somatic ethics" based on genetic knowledge of the body (N. Rose 2008a). The chapter argues that while these new modes of subjectification increasingly challenge the exclusionary function of IPRs, and begin to use them in new ways, the IP regime continues to separate their area of influence from the use of genetic materials in the bioeconomy. A new somatic ethics structures the subjects' conduct by encouraging individuals to donate their tissue and their medical information to research endeavours, generating valuable knowledge that can be used for governing supplements the economic circulation of 'life'.

The chapter develops a contrast between “research patients” and supposedly empowered “genetic” or “biological citizens”, and shows how the IP regime is currently limiting the participation of these active patients in decisions regarding the further use of information derived from their donations to biobanks or to other research projects. As a *regime for exclusion*, IPRs currently prevent disruptions to the bioeconomy, while for example the approach of ‘citizen’s science’ is trialling more democratic alternatives of data ownership. IP thus continues to govern for the market, while the pressure exerted by active patients is mounting. Importantly, these new subjectivities are mostly emerging in industrialised countries with advanced healthcare systems. However, a version of this challenge can also be traced on the international level, where new legal entities (or juridical subjects) such as Public-Private Partnerships (PPPs), Product Development Partnerships (PDPs), Patent Pools, and Medical Research Charities are also employing IPRs in new strategic ways.

This international dimension is then analysed in the sixth chapter. Here, IP’s function as a regime for exclusion is at its starkest level, entirely severing the connection between donors of genetic materials – located for example in developing countries – and the further use of these materials by companies located within industrialised countries. However, the coming into force of the Nagoya Protocol to the *Convention on Biological Diversity* (CBD) shows that some efforts address this disconnect, at least in the area of traditional knowledges and animal/plant genetic resources. While the relation between the CBD and TRIPS remains unclear, the IP regime’s relation to life and health is also coming under pressure within major international organisations operating at the intersection of life and the international economy: the WHO, WIPO, and the WTO. The chapter analyses an emerging conflict between the ‘right to health’ and IP, which could have the potential of delegitimising the IPRs regime’s exclusivity in an incremental way. An increasing critique relying on the argument of ‘market failure’ in certain developing countries may have a similar effect. The notion of market failure fundamentally challenges the assumptions underlying the neoliberal economy, arguing that measures based on the operation of the market were ineffective in the fulfilment of health priorities in certain contexts. These debates are currently only making relatively small interventions in IP’s international regime, but by inexorably introducing the problem of life into the field of IP, these interventions could be the basis for future challenges.

This chapter also engages with the problem of transposing Foucauldian ideas to the analysis of international relations, as debated between Kiersey, Weidner & Rosenow (2010) and Chandler (2010). It distinguishes between different interpretations of an international dimension of biopolitics, showing how some are more akin to ‘sovereign’ power exercises than others. Instead of making statements about a confrontation with ‘global’ biopolitics, the chapter seeks to implement an analysis of a specific site of contestation, which stretches across national boundaries and has a distinct international economic dimension in the shape of TRIPS. The exclusion of large parts of the world’s population from access to the products of research in the biotech and life science sector strongly invokes Selmeczi’s critique of the “abandonment” of those that do not count as part of the population, which she argues is constitutive of contemporary biopolitics (Selmeczi 2009). The international IP regime itself can be seen as a formal inscription of this abandonment, as this exclusive system does not account for the interests of large parts of the world’s population. The chapter however traces emerging challenges to this exclusivity, which are made in the name of life and health, and are eroding IP’s legitimacy.

The concluding chapter then places these analyses of the challenges faced by the IP regime’s encounter with a political sphere of life and health in context with the larger struggle between biopolitical challenges and a limiting ‘economic’ critique in neoliberal governmentality, showing how this places IP at the heart of the contested relation between the public sphere of governing and the private sphere that is “governed at a distance” (Miller and Rose 2008). At the intersection of life and the economy, the analysis in the previous chapters has revealed the precarious position of IPRs as a concession to research and development efforts of inventors, granting a temporary monopoly within the otherwise ‘free’ market of neoliberalism. Its new role in contributing to the management of the problematization of life begins to erode IP’s fundamental legitimation. In this process, the economic functions of IPRs are increasingly exposed to tension, as the “responsive” quality of IP law is beginning to stretch this field of law beyond its traditional content. Golder and Fitzpatrick point out that law can “[disrupt] itself through becoming receptive of resistances that constantly challenge its position, its content, its being” (Golder and Fitzpatrick 2009, 71). As IPRs increasingly begin to act as a tactics of government, contributing to the resolution of tensions between life and the market, their importance for the economy could be undermined by interventions that aim at their economic legitimacy. In this

way, the ‘problem’ of genetic life could fundamentally disrupt the economy of knowledge.

Chapter II Intellectual Property on Life Itself – Evaluating the Commodification Critique and its Limits

“At the centre of many of the issues that will be discussed [...] is the question of the commodification of knowledge.” (May 2000, 11)

“[Foucault’s] idea of self as enterprise takes the critique in a different direction, in that it understands the commodification of subjective experience not so much through ideas of passive consumerism, standardization and heteronomy, as through ideas of active differentiation, regulated self-responsibility and depoliticized autonomy.”
(McNay 2009, 62)

The discovery of the genetic code fundamentally altered the conception of life and reconfigured understandings of illness and well-being. It gave rise to new areas of study and also new sectors of the economy, which grew exponentially as the genetic conception of life was increasingly refined in the decades since the original discovery in the 1950s. The confluence of genetics and informatics continues to intensify the speed of sequencing and processing of genetic codes, as “the traditional ‘wet lab’ of molecular biology is being extended, augmented, and even replaced by the ‘dry lab’ of bioinformatics and computational biology” (Thacker 2004, 2). The proliferation of uses for the genetic code however also places questions of its ownership irresistibly at the centre of debates about conceptions of life and their relation to society and economy. As a result, IPRs in human genetic sequences are increasingly contested on the national and international level.

This chapter reviews existing literature on the issue of IPRs in human genetic materials, and their relevance for the biotech/life science sector in general. It finds predominantly critiques of the role of IPRs in the ‘commodification’ of life for economic use, a practice that has been interpreted as “biopiracy” (Shiva 1998) on the international level, and generally been criticised as a second “enclosure of the commons” of humankind (Boyle 2008; May 2010). However, this chapter argues that these critiques see IP’s role as a unidirectional tool of appropriation and value generation for the economy, and accord these economic relations foundational

primacy as a determining force for social relations. This analytical perspective does not account for the wider socio-cultural influence of the genetic conception of life, which gives rise to a new politics of life that contains other incentives than economic ones for participation in research projects. The emergence of a new “politics of life itself” (Franklin 2000; N. Rose 2007b) has been noted by a number of scholars, and has been explored with regards to the life science sector – however, the role of IPRs within this has never been comprehensively assessed beyond their function of providing commodities.

This thesis argues that in the confrontation with the genetic conception of life, IPRs are increasingly becoming part of the governmental management of life. The following chapters set out an analytical perspective that places emphasis on law’s function in providing the parameters for the market – they “govern for the market” (Foucault 2008, 121) – and then explores IP’s role in contestations between life and the economy on the level of knowledge, the subject, and new strategies questioning IP’s relation to life. Before turning to this analysis, this chapter introduces the existing two strands of critique, assesses the limits of the concept of commodification employed in these, and highlights literature on the life science sector focusing on its productive relation between the economy and life. Here the shortcomings of the commodification paradigm are mostly highlighted by reference to the power of the gift relationship in the area of healthcare – which cannot be accounted for in purely economically motivated terms.

1. Patenting ‘Life’ – Intellectual property and human genetic materials

The gene has become an ubiquitous point of reference for contemporary life, as constant news about research into genetic conditions and predispositions are promising the ultimate insight into the human body’s innermost secrets such as processes of aging, learning and healing (Dawkins 2006; Ridley 1999; Frank 2012; on processes of aging Corbyn 2015; debate on the moral implications of new capabilities in the “editing” of heritable human genetic sequences see *The Guardian* 2015; Lanphier et al. 2015; Hilton et al. 2015; “Genome Editing: CRISPR Controls Gene Expression” 2015; Liang et al. 2015; Sample 2015). The discovery of the gene is influencing the understanding of human life, of human potential and of human relations to other humans and to the environment. The genetic paradigm has

dominated research within the life sciences, displacing other research areas in the process (Kay 1993; H. Rose and Rose 2012). Large-scale prestigious research projects such as the Human Genome Project (HGP) captured the public's imagination and marked the beginning of a new era of research in a wide variety of fields within and beyond the life sciences, ranging from agriculture, food sciences, forensics, pharmacology, research in biofuels, to virology and various medical areas such as cancer treatments. Since the HGP's completion, the development of increasingly effective methods of sequencing and analysis of DNA has further intensified this influence of genetic scientific knowledge, which has begun moving beyond the specialist context of the laboratory as home testing kits and even sequencing machines are becoming increasingly available.³

Roughly at the same time as the rise of the gene, a new form of intellectual property emerged: the gene patent. This form of intellectual property on information derived from human, plant, animal, or micro-organism genetic materials was highly controversial since its inception in the 1980s, beginning with the patenting of an oil-dissolving micro-organism (*Diamond v. Chakrabarty* (1980) 447 U.S. 303). Subsequent very broad patent claims such as the *OncoMouse*TM raised concerns about the exclusionary effects of this practice, claiming in this case an entire “transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated Onco gene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage” (Jaenichen, McDonell, and Haley Jr. 2002, 8). Further notorious examples consisted of patents applications on basmati rice, traditional indigenous herbal remedies, agricultural seed materials, and also human genetic materials, as for example in the case of the surreptitious patenting of John Moore's genetic material (*Moore v. Board of Regents* [1990]).

In the unfolding debates about the implications of genetic research and the ownership of genetic materials, the pharmaceutical industry, researchers, philosophers, ‘bioethicists’, patients, IP lawyers, politicians, and national governments all contributed to ethical arguments. These debates resulted in slightly different regional approaches to the regulation of the patentability of human genetic materials, in which in theory every country can establish its own particular regime.

³ See for example a recent crowd-funded project aiming to produce an open-source real-time PCR (polymerase chain reaction) thermocycler, which not only amplifies specific segments of DNA, but can also turn this DNA into data (<https://www.kickstarter.com/projects/chaibio/open-qpcr-dna-diagnostics-for-everyone> accessed 26.11.2014). This machine is crucial for DNA analysis.

However, this changed in 1994 with the introduction of international minimum standards of patentability laid down in the *Agreement on Trade-related Aspects of Intellectual Property Rights* (TRIPS) as part of the World Trade Organization (WTO). In this treaty, a US model of IP law was implemented worldwide, at the behest of influential US industry interests (Sell 2003). IP has since become a highly charged topic in international negotiations, as these legal standards are mostly perceived to be in the interest of industrial countries, and are widely criticised for their detrimental effects on developing countries – especially in the context of pharmaceuticals and health (Hestermeyer 2007).

This chapter presents an evaluation of critiques made of IP's treatment of genetic conceptions of life, and argues that they are overly focused on the role of IPs within the economy, and do not take into account the wider political dimensions of the emergence of the gene (referred to later as “the genetic dispositif”) and the establishment of exclusive ownership over this knowledge. These dimensions will then be explored throughout the thesis, on the level of contestations over the recognized “truth” of life, of demands for participation and openness voiced by “active patients”, and of critical interventions made upon the international level, seeking to challenge the IP system's exclusivity in the name of health. This section first briefly explains the legal concepts establishing intellectual property rights especially in the form of patents, and then shows how the national and the international intersect in the IP regime guaranteed by TRIPS. After establishing this background, this chapter then turns to an evaluation of several strands of critiques.

1.1. IPRs in human genetic materials – ‘Inventing’ a commodity

Intellectual Property Rights comprise a range of different legal mechanisms for establishing ownership over abstract ‘intellectual’ creations – thus making an abstract idea or invention into a tradeable commodity. Without this, the distribution of knowledge would remain “non-rivalrous”, as knowledge does not diminish when it is distributed, unlike more conventional objects (Boyle 2008, 3). Making commodities out of information derived from ‘life’ pushes the boundaries of intellectual property, as the subsequent discussion shows. In this, the focus of this work rests predominantly on patents, which are the most important means of ‘owning’ information derived from human genetic materials. Copyright is involved in this area to a much more limited

extent.⁴ *Patents* are the tool that assure ownership over an idea, whereas *Copyright* is the means by which ownership of a particular way of expressing an idea is established, as for example in a novel or a computer programme (see May 2010, 5). Copyright is not in itself a new invention but rather creative usage of pre-existing concepts such a language. Patents confer a “limited monopoly” on the patentee “in return for the disclosure of technical information” (Bently and Sherman 2009, 335).

Patents are usually defined as “a monopoly which is granted for an invention after application to, and examination for patentability by, the Patent Office and lasts for a maximum of 20 years. To be patentable, an invention must be new, show an inventive step, be industrially applicable and not fall into one of the excluded categories of invention” (Colston and Galloway 2010, 4). Most important for IPRs in human genetic materials is the notion of the inventive step, which seeks to ensure that patents are granted for *inventions*, not *discoveries*. An invention is the creation of a novel product by a scientist/ inventor, whose creative effort warrants reward (see for example Jasanoff 2012, 165f.). Mere discoveries, on the other hand, are fundamental ‘truths’ that cannot be owned, as this would “inhibit competition and deprive the public of a truth that had always existed, only waiting to be uncovered” (Colston and Galloway 2010, 126; they give an example of the discovery of a new chemical element as one such “truth”).

This distinction may seem straightforward at first, but becomes most problematic in the context of human genetic materials, where a determination has to be made whether the human genome or individual genetic sequences constitute a discovery or an invention (see discussion in chapter IV). Even IP’s most basic precondition of the ‘inventive step’ is immersed in debates involving different interests and different interpretations of the truth over life. At stake in these debates is nothing less than the question of IP’s legitimacy in this area – and an entire economy of funding for research. This thesis does not seek to normatively decide this debate, but rather to provide an analytical perspective on debates surrounding parameters of IP that foregrounds contestations about truth contained in technical assumptions such as the inventive step, industrial applicability, or ‘novelty’. Rather than focusing predominantly on the economic role of IPRs in human genetic materials and their

⁴ There are also ways of establishing de facto control over genetic information by means of copyright, for example through ownership of the copyright over the programme showing information in the browser rendering the genetic sequence of the individual legible and usable (O’Riordan 2010, 9 and 21).

making of the commodity, this perspective can account for a wider variety of power exercises surrounding the creation of intellectual property over life – especially IP’s role in the normalization of knowledge and in the management of political challenges emerging from the predominance of genetic conceptions of life.

This analysis of the different roles of IP does, however, not seek to argue that IPRs do not fulfill the function of providing commodities. It rather argues against a primary focus on this role, which interprets tensions surrounding IPRs with reference to this role alone. This chapter shows that emphasis on the creation of commodities comes at the expense of a more detailed appreciation of the rise of genetic conceptions of life’s wider political implications – and the way in which this account of life presents problems for governing, negotiated especially in this legal field situated at the intersection of genetic accounts of life and the economy. The economy here becomes a project of government, which puts into place the parameters of the ‘free market’ and regimes such as IPRs, which can be used to ensure the appropriate functioning of this market. Thus, rather than arguing that IPRs are “commodifying life” because of demands of the market, this thesis reverses the analysis on IPRs as a constitutive part of laws governing for the market (see next chapter), arguing that they fulfill more functions in this process than the provision of commodities alone. In this, IPRs contribute to the management of problems for the governing of life while simultaneously maintaining objects for circulation in the economy.

1.2. IP: Connecting the national and international context

The establishment of an international IP system built on enforceable minimum standards in the early nineties gave soon rise to fierce criticism and controversy, as later negotiation rounds on WTO treaty amendments showed. The next few decades saw this previously relatively obscure technical area of economic law develop into a hotly debated issue, challenging for example its connection to health concerns and the relative imbalance of interests served by IP. Developing countries succeeded in securing a declaration on the relation between IPRs and public health in the Doha Round of WTO negotiations commencing in 2001, but this declaration fell short of actually introducing new options into the already established system (WTO 2001, see also chapter VI for details of changes that were nonetheless enabled by this declaration). In the field of genetic resources and traditional knowledge, indigenous

peoples increasingly challenged the use of IPRs on traditional indigenous knowledge and genetic resources gathered by bioprospecting operations across the globe. Separate treaties were drafted to respond to such concerns, for example the Convention on Biological Diversity (CBD) and its *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity* (2010), but are still not (to date) endorsed by some of the most important industrialised countries such as the US – which are most in favour of high IP standards and strong enforcement measures.

The history of TRIPS and the uneven distribution of IP-producing industries world-wide reveal a very strong interconnection between national and international agendas within the field of IP policy – especially where it comes to the influence of some very powerful industrialised countries such as the US. The standardisation in the field of IP law brought about by TRIPS was heavily influenced by these interests, which also continue to push for more stringent ('TRIPS Plus') agreements. As Sell points out, the TRIPS agreement was substantially drafted by a private pressure group called Intellectual Property Committee (IPC), consisting of chief executive officers of pharmaceutical, entertainment and software industries in the US, Europe and Japan (Sell 2003, 2; Tyfield 2008). In the TRIPS agreement's negotiation, these lobbyists set out to strengthen existing protection measures and succeeded in gaining government support for a highly protectionist new agreement based on already existing IP laws of industrialised countries, thus effectively globalising a previously predominantly national system reflecting the interests of industrialised states (Sell 2003, 2). A similar US-led undertaking can currently be witnessed in the negotiations seeking to introduce TRIPS Plus standards in international agreements such as the *Anti-Counterfeiting Trade Agreement* (ACTA), the *Transpacific Partnership* (TPP), and to some extent also in the current negotiations between the US and the EU as part of the *Transatlantic Trade and Investment Partnership* (TTIP) (Sell 2008; Abbott 2009; UNAIDS 2011; Geist 2010).

The biotech sector also traverses national boundaries in a variety of other ways. Biotech companies, for instance, are most likely based within countries with a beneficial IP system. One early high-profile example is *deCode Genetics*, which set up and ran the Icelandic Biobank – a private corporation formed under US law but with its physical location in Iceland. This is a common occurrence in the biotech sector, where "most biotech companies in the world are given a fictitious Delaware

location for legal, tax and patent advantages” (Pálsson and Rabinow 1999, 14). A large proportion of biotech companies are thus actively seeking out the US IP system, which is less restrictive than the European approach especially in the area of human genetic materials. For example, since the *Bayh-Dole Act* (1980), the US system allowed for IPRs being derived from publicly funded research projects, “[facilitating] the transfer of technology between academe and industry in the United States, and thereby [enabling] rapid commercialization of basic research problems” (Rajan 2012, 2). This gave rise to the “entrepreneurial university” such as Stanford, which gave a “huge spur to the overall commercialization of biotechnology, and specifically to the development of Silicon Valley”, and has “a full-fledged technology-licensing office that focused exclusively on marketing university inventions” (Ibid., 3, this notion of the entrepreneurial university is now also being implemented outside of the US). Generous IP provisions such as these gave rise to an extraordinary influence of the US within the international biotech sector. Beyond this particular expansion of private interests, medical research in general has also become internationalized, as drug trials are increasingly recruiting test subjects from countries in which the population is not already exposed to a large number of pharmaceuticals, trials can be conducted more cheaply, and ethical standards are less strictly enforced (Petryna 2006, 37 and 42). Within this complex intersection of national and international private and public interests, IPRs’ economic role has been analysed from a variety of perspectives, as the next section shows.

2. Critiques of the “commodification” of life

The patenting of genetic conceptions of life has been the focus of several strands of critical analysis, with different emphases on either its detrimental effects on developing countries on the international level or on the general prevention of the spread of knowledge throughout society. This section shows how both lines of argument foreground the economic role of IPRs of forming commodities for exchange. This evokes an economically determined order, in which the relations of the market dictate regulations (such as IPRs) that are beneficial for them. In this way, the requirements of the market determine the use of IPRs as either an “instrument of conquest” (Shiva 2001, 11), acquiring new materials from around the world without offering compensation, or as a tool enabling the expansion of the capitalist system

through a “new enclosure of the commons” (Boyle 2008; May 2010), which creates private property out of previously open and shared resources. Both emphasize the reinstating of “proper” bounds of property”, which “bind patent law and its opponents to the very distinctions between nature and culture, or discovery and invention, that biotechnology has rendered transparent or implausible” (Pottage 1998, 745).

Both strands of critique contain strong normative assumptions, as one highlights neocolonial practices and the other deplores the loss of the common heritage of mankind to a capitalist system operating through individual monopolies. This section will briefly set out both critiques, and then evaluate the focus on life’s “commodification”. In this it argues that this perspective neglects to explore the wider cultural and political significance of the genetic vision of life, which has more complex implications than the unidirectional process of commodification can account for, giving rise for example to new practices of the self that can either challenge or promote IPRs. The chapter then turns to a number of more recent analyses of the biotech sector, which have begun to explore these political implications.

2.1. Denouncing “biopiracy” – IPRs as international “instruments of conquest”

Forceful critiques of the international dimension of the IP regime have decried IP’s role in “biopiracy”, referring to a mechanism by which knowledge or materials that are indigenous to one place can be appropriated by private companies from a more industrialised country. Shiva for example argues that IPRs historically started out as “instruments of conquest” and that “[p]atents which refer to knowledge as ‘property’ remain an instrument of colonization” (Shiva 2001, 11 and 18). According to Shiva, “Biopiracy refers to the use of intellectual property systems to legitimize the exclusive ownership and control over biological resources and biological products and processes that have been used over centuries in non-industrialized cultures” (Ibid., 49; see also Odek 1994; Sarma 1999; Aoki 1998; Mushita and Thompson 2007; Mgbeoji 2006; Robinson 2010). Common examples include the patenting of traditional medicinal knowledge and plants, for instance the (attempted) patenting of plant species such as Basmati rice, or the patenting of the Kwao Krua herb from Thailand – and larger ‘bioprospecting’ missions gathering human genetic or plant materials from remote areas across the globe (Robinson 2010; Mgbeoji 2006).

Stanford's Human Genome Diversity Project (HGDP) became particularly controversial as it sought to gather human genetic materials from remote tribes in the quest for the discovery of different genetic markers.

Odek likens these practices to “the Age of Exploration, [when] researchers and travelers [...] transported discovered plant species back to their own countries as new foods and raw materials for plant breeding”, and denounces this “uni-directional and uncompensated appropriation” (Odek 1994, 141 and 145). He emphasises that “the characterization of such acts as piracy serves as a normative assertion by developing countries that they have an entitlement to their plant genetic resources” (Ibid., 145). Robinson points to the origins of the term in language used by the NGO Rural Advancement Foundation International (RAFI) (Robinson 2010, 14; Mgbeoji 2006, 12), stating that “[t]he use of the biopiracy discourse in these contexts is an indication that the term is politicized, reactive, and, in many cases, imprecise” (Robinson 2010, 15).

Biopiracy criticises the commodification of indigenous pre-existing knowledge and materials through a Western hegemonic system of appropriation. This system employs “mechanisms of appropriation” which conceptually exclude pre-existing forms of knowledge, characterizing “certain natural materials that indigenous and local communities have cared for, preserved, improved, and developed as mere ‘wild’ species” and “while the products of formal knowledge systems [...] [are being] protected as ‘property’, those of informal, traditional systems have been tagged the freely available ‘common heritage of humanity’” (Roht-Arriaza 1995, 292). This mechanism is “[p]erhaps the most prevalent and insidious form of appropriation of indigenous knowledge and resources”, which “systematically exclude[s] the knowledge and resources of local communities, farmers, and indigenous people” (Ibid.; Sarma 1999, 115). This exclusion “works against indigenous groups primarily due to various procedural qualifications, such as the requirement of written documentation of knowledge or invention under US patent laws” (Sarma, Ibid., 116). The result is that “[t]he intellectual contribution of societies and communities which have not been motivated by the objective of profit is thus exploited, but not recognized” (Shiva 1998, 55).

These effects are not accidental side effects of the IP system, as Shiva points out:

“Western patent systems were designed for import monopolies, not for screening all knowledge systems to exclude existing innovations and establish *prior art* in other cultures. [...] *Terra nullius* has its contemporary equivalent in ‘Bio-Nullius’ – treating biodiversity knowledge as empty of prior creativity and prior rights, and hence available for ‘ownership’ through the claim of ‘invention’.” (Shiva 2001, 49; emphasis in original)

The procedural hurdles of IP and their inbuilt preference for “formal” knowledges are thus found to be part of an economic system that profits from resources gathered around the world in a unidirectional movement of appropriation. Biopiracy thus leads to a “pattern [that] is becoming depressingly familiar: resources flow out of the Southern regions and are transformed by Northern entrepreneurial authors and inventors into intellectual properties, which in many cases are priced so high that the people from whom such knowledge originated cannot afford to license them” (Aoki 1998, 27). Hamilton calls this “old-fashioned, Western-style imperialism” (Hamilton 1996, 615).

Treaties such as the Convention on Biological Diversity (CBD) and the Nagoya Protocol’s system for access and benefit sharing are designed to prevent these exploitative tactics from reoccurring. Chen, for example, argues that the CBD lets “source countries exert complete control over the physical, phenotypical layer of information in bioprospecting” (J. Chen 2006, 12). As a result, biopiracy “must be consigned to the realm of ‘rural’ legend”, as “an appropriately utilitarian view of property and its relationship to each layer of biological information [...] dissolves any allegation of Biopiracy” (Ibid., 5 and 6). According to Chen, problems only arise when the national government fails to do its job ‘properly’: “Responsibility for this plant’s [the jaborandi plant in Brazil] decline does not rest with the multinational pharmaceutical company merely because it has developed anti-glaucoma drug from jaborandi. Rather, the government of Brazil is accountable for its failure to control access to jaborandi in its natural range or otherwise to regulate its harvest” (Ibid., 13).

Chen’s understanding of the relation between IP and knowledge highlights the common response to accusations of ‘biopiracy’: an adjustment of the parameters of the commodification procedure. This side-steps biopiracy’s fundamental normative

critique of hegemonic knowledge structures.⁵ However, the biopiracy critique also understands this knowledge structure as determined by an economic system, and predominantly contests the legitimacy of the appropriation (see for example Aoki 1998, 46ff.). Shiva for example criticises the CBD and access and benefit projects as “merely a sophisticated form of Biopiracy” (Shiva 2001, 63). The fundamental normative complaint is that these also “[take] the biodiversity and intellectual heritage of indigenous communities and [convert] it into commodities protected by IPRs” (Ibid., 64). Thus debates focus on the definition of the “proper” bounds of property” instead of interrogating IP’s function in the field of biotechnology on a deeper level (Pottage 1998, 745).

This focus precludes a more detailed engagement with IPRs as a site of complex political contestation, in which IP’s role can be understood as less unidirectionally determined by a global economic hegemony but rather the site of various power struggles, such as for example between different knowledges – even between different genetic conceptions of life, as chapter IV of this thesis points out. IP’s relation to knowledge is not straightforward, as shown in the US Supreme Court’s endorsement of genetic-informational conceptions of life in the *Myriad* case, which entailed the abolition of certain types of gene patents. This decision cannot be explained with reference to commodification alone, but rather needs to be seen in context with challenges produced by a political dimension surrounding genetic conceptions of life, as this thesis argues. The extraordinary success of the genetic view of life had much broader effects than just the enabling of the commodification of life, and continues to create problems that are constantly requiring new forms of governing. This understanding of “life as a productive force” (Yoxen 1981) in the wider sense will be set out below, after a discussion of IPRs as a tool for the enclosure of the commons – predominantly by means of commodification.

2.2. *The “new enclosures” and the political economy of commodification*

Shiva criticised bioprospecting not only as a form of biopiracy, but also because it “leads to the enclosure of the biological and intellectual commons” (Shiva 2001, 64).

⁵ Chen also exaggerates the reach of the CBD and the Nagoya Protocol, which only came into force on 12.10.2014. The US are signatories but have not ratified these agreements. The relation of the CBD and TRIPS is also entirely unclear. Ongoing deliberations at the WTO have thus far not reached a clear position, especially in the area of Art. 27.3b TRIPS on traditional knowledge and biodiversity (see current state of the debate and list of documents at WTO 2015a).

This alludes to another critique of the IP system, referring to the historical process of the enclosure of the commons, which occurred between the 15th and 18th century in England. In this process, community-owned land was suddenly transformed into the exclusive property of an individual, who then had the power to own and to derive the benefits from it (May 2010, 12; Boyle 2008; Boyle 2003). Proponents argue that this process is occurring again, in a new enclosure of humankind's 'commons', which are for example biodiversity, genetic resources, the human genome, the Internet and knowledge in general (see for example Halbert 2005; Dickenson 2013, 193; to some extent also Marlin-Bennett 2004; Zeller 2007).

The concept of the 'new enclosures' is often used with reference to copyright and the way in which it increasingly infringes on knowledge exchange in the area of information and communication technology (Lange 1981; 2003; Benkler 1999; Carstensen 1999; Travis 2000; P. Evans 2005; Boyle 2003, 37, Footnote No. 12), whereas the 'biopiracy' argument is prevalent with regards to the area of agriculture and medicine. References to the 'commons' and their 'enclosure' evoke the historical background of this movement in the same way as references to imperialism and colonial practices. This is highly emotive and effective in setting the scene for their accounts, but relies on importing a particular normative position. Much of the literature concerning the second enclosure movement focuses on the appropriate division between what ought to be openly available and what can be legitimately 'enclosed' and be turned into private property. Both concepts in effect question the legitimacy of the IP regime where it comes to the common heritage of mankind – contained in indigenous knowledges, biodiversity, the internet and open source software products. Both approaches refer to IP's role in this commodification as entirely determined by its function in the economy. While the 'biopiracy' debate follows a post-colonial line of argument, the 'new enclosures' literature is modeled on the libertarian tradition of Locke's writings and often engages with US civil rights standards and copyrights' possible infringement on these standards (see for example Benkler 1999; Travis 2000).

May's comprehensive and thorough political economy of the global IP regime argues that "the recognition of such commodification as enclosure has become more than a merely spasmodic polemic and is now one of the key tropes of those who seek to critique and resist the expansion of the realm of intellectual property" (May 2010, 12; see also Halbert 2005, 112 ff.). He points out that the allusion to the historical

background of 15th to 18th century England serves to draw attention to the *artificiality* of the boundaries around private property. May finds that IP is “allied to the complex institutional arrangements of modern capitalism” and argues, “intellectual property enables the expansion of capitalism into areas hitherto regarded as a realm outside direct exchange relations” (May 2010, 11 and 48). His political economy of IPRs employs a complex analysis of the expansionary logic of capital with a neo-Gramscian emphasis on the function of ideology (Ibid., 47)⁶, exposing in particular IP’s reliance on the “construction of scarcity” in the otherwise non-rivalrous area of knowledge (Ibid., 23; May and Sell 2005; May 2006).

However, this concept of commodification or ‘reification’ tied to a Gramscian-Marxist economic analysis sees IP law as entirely determined by its function for the (expansionary) logic of capital. May is critical of IP’s narrow focus, and argues against the “manner in which intellectual property’s supporters have sought to reduce the political economy of IPRs to a set of technical problems with little regard for [...] the wider question about the social construction of intellectual property and its associated markets themselves” (May 2010, 148). However, in a neo-gramscian/marxist analysis, ideas remain conceptually tied to the determining force of the relations of the market, and are seen as primarily and exclusively conducive to the maintenance of them. May highlights that “[t]he reification of IPRs into natural rights of individual innovators [...] obscures the interests served by the protection and enforcement of [...] intellectual property” (Ibid.). He thinks mostly of interests such as the maintenance of a “market advantage” (Ibid.). This thesis argues that the overwhelming focus on the economic function of IPRs as part of the market obscures a wider political struggle surrounding the relation between knowledge and life, in which they are also fundamentally involved.

Bollier’s analysis of IP’s commodification of life begins to draw attention to the limits of an exclusive focus on economic exchange mechanisms and the necessary commodification for these mechanisms. He argues that certain areas

“require personal participation in a *gift economy*, where the coin of exchange is not money but freely given gifts (personal attention, acts

⁶ This theoretical approach is an adaptation of the perspective used in the first edition of May’s book, which connected material forces and ideas in a dual-dialectic movement of change according to Hegel and Marx, moving between “contradiction and change” (May 2000, 39).

of kindness, sacrifices of time). Markets and money are impersonal. Gift exchange is the only real way to achieve the satisfactions of family life or sexuality” (Bollier 2003, 23; emphasis added).

This notion of a separate gift economy has been used widely in the field of anthropology to highlight alternative exchange mechanisms, which provide stronger incentives for donations of blood and body tissue than a purely economic monetary exchange mechanism (see Titmuss 1997; Eriksen 2001; Waldby and Mitchell 2006; Lock 2002; Sharp 2000; Nelkin and Andrews 1998). This concept emphasises powerful incentives such as *altruism* for the donation of tissues and information, and for participation in patient groups. Crucially, these ‘economies’ defy the rules of the market: “It is precisely the effectiveness and speed of gift economies in facilitating certain kinds of value-exchange that have so alarmed entrenched industries” (Bollier 2003, 30). While analyses seek to highlight interpersonal values and relationships that are not captured by the notion of the market, they understand this contrast as a “*dichotomy of gift and commodity*” (Waldby and Mitchell 2006, 8, emphasis added).

However, attempts at categorizing IPRs as gift or commodity reveal a more complex situation. IPRs on information derived from human genetic materials incorporate elements of both categories of the commodity and the gift, as IP ‘commodifies’ information in a manner that actively separates any connection between the donor and the owner of IPRs derived from the donation. Titmuss pointed out that the free donation of blood ensured a higher quality of the donation compared to that of paying donors— arguably because of “an altruistic motive” (Titmuss 1997, 124 and 125). But in the case of IP, donors are “legally excluded from any stake in [...]IP’s] profitability” (Waldby and Mitchell 2006, 24). Instead of giving rise to the socially beneficial effects of the gift relation observed by Titmuss in the area of blood donation, IPRs preclude donors from any form of societal recognition – especially on the international level. In the case of IP, the dichotomy of gift and commodity results in a rather cynical situation, in which “[Titmuss’] strategy to make the human body a bulwark against the commodification of social life, a strategy now institutionalized in bioethical procedure, has simply rendered the body an open source of free biological material for commercial use” (Ibid.).

This opportunistic exploitation of altruistic motives for donation goes beyond a dichotomous relation between gift and commodity, and needs to be understood as

more than a coincidence. While the contrast between commodity exchange and gift economies can reveal some of the limits of an analysis determined by a focus on economic relations in a market, it cannot further explain the connection between the “moral enforcement” of donations and the exploitative function of IPRs with regards to donations. Rather than producing societal cohesion, the moral duty to provide voluntary donations here becomes embroiled in a different political project, as chapter V of this thesis argues. Using the example of active patients who participate in research in the endeavour to improve their own condition, this chapter points out that patients are encouraged to take responsibility for their physical condition, now defined in genetic terms according to a new “somatic ethics” (N. Rose 2008a), and become actively engaged in improving their self in an entrepreneurial manner (McNay 2009). Focusing on reinstating a more ‘appropriate’ kind of property cannot account for the way in which these patients challenge exclusion from research by using IPRs in order to promote their own well-being. This behaviour confronts IP with a new ethics based on genetic truth, which challenges IP’s exclusionary role towards patients, preventing them from participating in the use of their donation. After briefly drawing attention to the limitations of the commodification critique’s focus on market relations as the determining force of IP’s relation to life, the last section of this chapter then shows how other analyses of the biotech/ life science sector have begun to engage with the ways in which “life as a productive force” (Yoxen 1981) is harnessed by the economy but also continues to produce problems and challenges for governing.

2.3. The Limits of the Commodification Paradigm – ‘Forgetting’ Life

Critical perspectives on IP’s ‘commodification’ of life thus debate the appropriateness of the underlying parameters of IP, and in this way “serve to reproduce the very processes that they criticise” (Pottage 1998, 758). This focus on the parameters of commodification engenders an economically determined understanding of social relations, and marginalizes a wider politics of life. A deeper understanding of the notion of ‘commodification’ derived from the work of Marx and the Frankfurt School reveals the extent of the economic determination implied in the commodification critique. While IP’s role in the commodification of life certainly needs to be seen critically, the “paradoxes” (Waldby and Mitchell 2006, 163) at the intersection of the

economy and knowledge over life demand a less unidirectional understanding of IP's role in this. Genetic conceptions of life also challenge IPRs, by undermining the distinction between inventions and discoveries (see chapter IV), and by giving rise to new demands on laws and policies regarding the treatment of life (see chapter V and VI). This thesis argues that in the management of these challenges, law takes on a new role as a mode of governing tensions – which goes beyond IP's unidirectional role in the economy as a tool for commodification.

Marx's critical analysis of capitalism centres on the relation of labour to the commodity, which is constituted by a process of abstraction or alienation not from its use or purpose, but with reference to the amount of human labour spent on it (Marx 1990, 127). This objectification of labour in the commodity gives rise to its “fetish character”⁷:

“A commodity is [...] a mysterious thing, simply because in it the social character of men's labour appears to them as an objective character stamped upon the product of that labour; because the relation of the producers to the sum total of their own labour is presented to them as a social relation, existing not between themselves, but between the products of their labour.” (Ibid., 164)

The objectification of “men's labour” in the commodity by means of contingent processes of value attribution is here seen as the basis for social relations. It “transforms every product of labour into a social hieroglyphic... [which] [l]ater on, men try to decipher [...] to get behind the secret of their own social product” (Ibid., 167). The process of commodification thus has objective and subjective implications:

“*Objectively* a world of objects and relations between things springs into being [...] [whose] laws confront [man] as invisible forces that generate their own power. *Subjectively* [...] a man's activity becomes estranged from himself, it turns into a commodity which, subject to the

⁷ Marx points out that “[a]s the commodity-form is the most general and the most undeveloped form of bourgeois production [...] its fetish character is still relatively easy to penetrate” (Marx 1990, 176). The same kind of fetishism operates also in more particular forms of exchange, such as the Monetary System and capital in general.

non-human objectivity of the natural laws of society, must go its own way independently of man just like any consumer article.” (Lukács 1971, 87)

This determination of the social realm by a system of meaning formed with reference to the exchange value of the commodity is decisive for the understanding of critiques of commodification – which thus focus their critique on a sphere of politics fundamentally determined by the exchange value of commodities. Crucially, this critical focus on commodification entails a marginalisation of understandings and content of social relations that do not fit this economic rationale, as the processes of abstraction already entail a “forgetting” of those less commodifiable contents. As Adorno and Horkheimer point out, “[a]ll objectification is a forgetting” (1979, 230).

The use of the concept of commodification in critical theory thus serves as a reminder of the processes of abstraction and alienation involved in the constitution of the commodity, and the net of social relations that emerges from this process, enveloping the individual. The commodification of human tissue, in extension, folds the individual into these relations (determined by exchange value) on the level of physical existence, and critiques focus on the ever-increasing sphere of this economically determined net of social relations. This critique of commodification has a particular normative content, as Honneth notes:

“it signifies a type of human behavior that violates moral or ethical principles by not treating other subjects in accordance with their characteristics as human beings, but instead as numb and lifeless objects – as ‘things’ or ‘commodities’.” (Honneth 2005, 94)

Importantly, pervasive “invisible forces” created through economic relations of exchange are “confront[ing] [man]” (Lukács 1971, 87) and bringing about these morally reprehensible effects of commodification. From this perspective, IP’s economic role on the one hand confronts the individual as an abstract regime that is virtually unchangeable, and on the other, turns the subject’s involvement in research into a commodity which “must go its own way independently of man just like any consumer article” (Ibid.). In this vein, Haraway for example criticises IP as “the kind of relationality that poses as the-thing-in-itself, the commodity, the thing outside

relationship, the thing that can be exhaustively measured, mapped, owned, appropriated, disposed” (Haraway 1997, 8). But she also notes that this relationality prefers measurable and knowable content at the expense of all other “bumptious” qualities of nature and life, which are sidelined (Ibid., 135) – for example in the overwhelming focus on the mapping of the human genome, and the discarding of “junk” DNA.

This ‘forgetting’ or dismissing of a vast array of nature’s ‘content’ highlights IP’s reliance on measurable forms of knowledge, but it also assumes a clear unproblematic complementarity between genetic understandings of life and IP, and does not further complicate this relation. But genetic sequences, as the *Myriad* judgement shows, can pose significant problems to the IP regime, which in response struck a compromise ensuring some patentability while also acknowledging the informational content of genetic sequences. Also, as chapter V shows, patients often freely volunteer their genetic information and even in some cases actively patent their own condition to exert control over research in this area. This thesis argues that these uses of IP require a different perspective, which places emphasis on changes in the use of IPRs beyond the sheer provision of commodities for the market.

Foucault’s critique takes a “different direction” to that of the Frankfurt School, especially where it comes to the construction of notions of selfhood (McNay 2009, 62; Burchell 1993). It “understands the commodification of subjective experience not so much through ideas of passive consumerism, standardization and heteronomy, as through ideas of active differentiation, regulated self-responsibility and depoliticized autonomy” (McNay 2009, 62). Instead of looking at processes of homogenisation through the production of false freedoms, Foucault’s accounts look at how processes of “active differentiation” for instance encouraged by the notion of the “self as enterprise” give rise to a more resilient neoliberal system (Ibid., 63). As the next chapter sets out in more detail, this productive way of governing through inciting “active” forms of self-actualisation is explored on three different levels in the remainder of this thesis, exploring the contributions of IP law to the governing of life on the level of knowledge, the subject, and the exercise of power. An emphasis on processes of identity formation and governance has also been applied in some recent analyses of the life science/ biotech sector (N. Rose 2007b; Rajan 2006; Cooper 2008; Rouvroy 2008). While none of them focus on the role of IP in this context in a

comprehensive and rigorous manner, the last section of this chapter shows how they account for the wide influence of the genetic vision of life in their analyses.

3. “*The Politics of Life Itself*” – Moving beyond commodification?

Lately the focus of analyses of the life science/ biotech sector has turned towards different ways in which value is generated in this area, and to a specific political economy emerging around life and value – in the Foucauldian sense of an economy building on a “knowledge [...] of government [that] is absolutely inseparable from that of a knowledge of all the processes related to population in its larger sense” (Foucault 2000, 217). This marks a turn away from critiques focusing on commodification, and begins to explore an emerging politics of “active differentiation, regulated self-responsibility, and depoliticized autonomy” (McNay 2009, 62) that promotes the neoliberal economy’s reach in a productive manner. However, studies of IP’s role in this sphere continue to concentrate on processes of commodification, despite growing attention to facets of productivity in the life sciences. In this general turn towards a political economy focused on governing life’s “productive force” (Yoxen 1981), scholars have increasingly drawn upon Foucault’s concept of biopolitics – at times in a more metaphorical manner, illustrating the fact that the life sciences’ interaction with ‘life’ has a political dimension (Lock 2001; Haraway 1997; Lock and Nguyen 2010), and at times more comprehensively (N. Rose 2007b; Rouvroy 2008; Thacker 2005a; Rajan 2006). IPRs are usually mentioned in these studies as one of the means by which value is being generated (and commodified) in this area. Their particular complex role in the governing of life has to date not been at the centre of such an analysis. However, this focus “on the emergence of a new genomic governmentality” (Franklin 2000, 188) shows how the biotech sector’s interaction with the productive quality of life can be analysed outside of the commodification paradigm.

3.1. ‘Life as a Productive Force’ – Capturing the politics of the bioeconomy

A number of analyses of the biotech sector begin by pointing out that instead of an inevitable development, the historical emergence of molecular biology in the life sciences had a distinct political dimension (Yoxen 1981; Kay 1993; H. Rose and Rose 2012). Yoxen sets out “the history of molecular biology as a research programme and

as a technological project – formed, organised and regulated by economic and political forces” (Yoxen 1981, 67). In his account of the formation of molecular biology as a discipline, he shows how “science managers” (Ibid., 88 ff.) selectively funded one direction of research amongst many, which studied life based on “the concepts of ‘information’ and ‘program’ [...] [which] draw[s] attention to the fact that our current rules of biological thought direct us to a specific level or mode of interaction in living nature” (Ibid., 70; also Kay 1993). This direction, Yoxen argues, was

“not only about new institutions, new techniques and new styles of research. It has also allowed the formation of new conceptions of life, nature and humanity, which are fundamentally important to both the pursuit of the research itself and its relation to contemporary society” (Yoxen 1981, 69).

In this way, molecular conceptions of life can be understood as being productive of more than just economic value, but are “a productive force” (Ibid., 1981) of understandings of the self and of an entirely new socio-cultural frame of reference for the governing of populations and the self.

Yoxen draws attention in particular to “the reductive shift to molecular processes” and the treatment of “nature as a program” in the promotion of molecular biology (Ibid., 77 and 101; see also Boyle 1996; 2008; Thacker 2004; 2005a; Nelkin and Lindee 1995; Kay 1993; 2000; see also chapter IV). The notion of the code has become central for the understanding of life at its intersection with information technology, as Thacker argues (Thacker 2005a, xx), and given rise to a range of new entities of “biomedia”, in which bioinformation is being stored and generated, for example in Biochips (used for the automation of repetitive laboratory tasks) and in BioMEMS (biomedical microelectromechanical systems, see Thacker 2004, 63 ff.). Landecker’s account of “the practice of growing living cells outside the body in a laboratory” shows how the life and the components of the human body have been transformed into entities that can be mass-produced and lead an immortal existence away from the donor, within the confines of the laboratory – thus changing “practices of plasticity and temporality of living things” (Landecker 2007, 1).

The shift to the molecular level of knowledge entailed “a redefinition of life: life as meaning” (N. Rose 2007b, 44). Undoubtedly, the emergence of these technical capabilities for the long-term storage, indefinite replication, and global distribution of cell lines gave rise to a new industrial sector, in which IPRs enabled the integration of life into the economy. But the promotion of one research agenda over others also points to this vision of life’s contingency on a particular programme. This affected the conception of ‘life’ in fundamental ways, as new living entities such as immortal cell-line were created in laboratories. It also affected lived experience beyond the confines of the laboratory, as the notorious case of the HeLa stem cell line shows. In 1951, particularly aggressive cancer cells were taken from Henrietta Lacks before her death without her knowledge or consent, and were developed into the highly successful immortal HeLa cell-line – and “have now been living outside her body far longer than they ever lived inside it” (Skloot 2011, 4). The development of this new living entity continues to cause controversy, and claims of Henrietta Lacks’ family for some form of limited control over the use of this very identifiable genetic material have only very recently been acknowledged in debates around the release of HeLa’s genome sequence (see Skloot 2013; Hudson and Collins 2013; Collins 2013). This cell-line was not patented, but its long-term implications for the Lacks family show how the development of these entities have effects far beyond their economic use, deeply affecting the identities of individuals and families.

Rose argues that on the basis of information generated in the laboratory, “we are increasingly coming to relate to ourselves as “somatic” individuals, [...] as beings whose individuality is, in part at least, grounded within our fleshly, corporeal existence, and who experience, articulate, judge, and act upon ourselves in part in the language of biomedicine” (N. Rose 2007a, 26). IP is thus becoming a contentious issue within a wider political economy of the molecular conception of life, situated at the intersection between economic circuits and knowledge that is increasingly important for the self-actualisation of “somatic” individuals. At this intersection, this thesis argues, IPRs are fulfilling more than a unidirectional function of creating commodities, and are rather involved in the governing of the “problem” in the sense of a “problematization” (Foucault 1994, 114) of life.

3.2. A “new genomic governmentality”

More recently, a number of scholars noted the particular problem of governing life in its molecularised form, and increasingly turned to Foucault’s notions of biopolitics and governmentality for their work on a new “politics of life itself” (Franklin 2000; N. Rose 2007b) based on knowledge created in the laboratory. Here, Franklin argues that “[w]e are currently witnessing the emergence of a new genomic governmentality” (Franklin 2000, 188). This refers to the emergence of new form of governing based on this knowledge, derived from Foucault’s concept of a new art of governing or *governmentality* (Foucault 2000; see next chapter). This thesis analyses how IP’s treatment of life could be better understood with reference to this concept of governmentality, in which new priorities for governing such as life can challenge the operation of economic relations. The politics of life ‘itself’ in the life science/ biotech sector have been explored specifically (Cooper 2008; Rajan 2006; Rouvroy 2008), and in more general terms (Rabinow 1996; 1999; Rabinow and Dan-Cohen 2005; Rabinow and Rose 2006; N. Rose 2007b; Dillon and Reid 2001; 2009; Dillon and Lobo-Guerrero 2008; 2009; Elbe 2009). These and other uses of Foucault’s ideas will be discussed in the next chapter, where the parameters of this governmentality and its increasing emphasis on biopolitical strategies for the governing of life will be set out.⁸ The discussion here merely seeks to point to some studies and their conception of the politics of molecularised life in order to provide a contrast to the commodification critique’s perspective on IP.

The issue of IP is raised consistently within these studies of molecular “life itself”, but mostly with regards to its function of creating commodities for the economy. There is to date no comprehensive study of IP’s contribution to the governing of life within the life science sector. However, Pottage’s article on “Genes, Patents and Bio-politics” explores IP’s function in stabilizing hybrid genetic concepts of life in order to establish “singular scientific ‘fact[s]’”, thus understanding patents as “vectors” (Pottage 1998, 752 and 749). But he connects this to a notion of “governing” only in so far as “[bio-political programmes] treat the distinction [between norm and nature] itself as a provisional programme which serves to govern their own operations” (Ibid., 747). Yet this statement on the intermediary position of

⁸ Bruno Latour (1987) and Sheila Jasanoff’s (2005; 2004) work in the area of Science and Technology Studies (STS) are other noted sociologist that discuss broad topics such as the influence of politics on science and vice versa, but their work cannot be considered here due to space constraints.

biopolitical programmes can hint to the mode in which IPRs are understood to function as a “tactics” of government (Foucault 2000, 211) by this thesis. IP’s contribution to the management of the individual’s involvement in the bioeconomy and to the normalization of knowledge consists in the negotiation of tensions between the different priorities of life and the market in a neoliberal governmentality, thus “[engaging] responsively with exteriority” (Golder and Fitzpatrick 2009, 71, see next chapter).

The engagement of other studies on the biotech sector with Foucauldian concepts can range from a mere mention of Biopolitics to a more in-depth exegesis of an emerging ‘politics of life’ and its relation to the economy. Franklin’s work introduced the notion of “life itself” and expressly drew on Foucault, but then turned towards highlighting the pervasive cultural reception of genomics rather than towards connections with the economy. Rajan’s comparative study of the life science sector in India and in the US contains a more direct engagement with the notion of biopolitics. He explicitly sets out to combine the Marxist concept of capital with the Foucauldian concept of biopolitics, arguing “that the life sciences represent a new face, and a new phase, of capitalism and, consequently, that biotechnology is a form of enterprise inextricable from contemporary capitalism” (Rajan 2006, 3). In this phase, “*Biocapital*”:

“operates explicitly in two distinct yet simultaneous analytic frames: one the one hand, as the circuits of land, labor, and value (in a classic Marxist sense) that are inhabited by biotechnological innovation and drug development; on the other hand, as the increasingly constitutive fact of biopolitics in processes of global capitalism. In other words, on the one hand, what forms of alienation, expropriation, and divestiture are necessary for a ‘culture of biotechnology innovation’ to take root? On the other hand, how are individual and collective subjectivities and citizenships both shaped and conscripted by these technologies that concern ‘life itself’?” (Ibid., 78)

Rajan’s comparative study of biotech companies in India and the US highlights the coexistence of the economy and life as priorities for governing – as also set out in the

next chapter. He also points out the fundamental impact of genetic knowledge on individual and collective subjectivities.

However, his discussion of IPRs focuses on the “fluid and constantly contested boundaries between what constitutes the public domain and what private property” (Ibid., 59). His understanding of IPRs in this is influenced by Coombe’s emphasis on IP “as a constitutive object in commercial and popular lifeworlds, as a source and sink of social power” (Ibid., 65; Coombe 1998) – thus in a way that goes far beyond the role of providing commodities. But he focuses on challenges emerging in the public policy sphere, as the question of IP is deemed to have been “settled” in law and thus not discussed as a part of bioethics (Rajan 2006, 64). Rajan traces the “fluidity” of IPRs in the complex positions of India and the US in the biotech sector, and shows that these countries’ presumed positions regarding IPRs are far from certain. This shows surprising fluidity in the parameters of the making and enforcement of IP as a commodity. In contrast, this thesis inspects IP’s “fluidity” in a more directly governmental context, arguing that this flexibility enables IP to negotiate tensions surrounding the relation of knowledge over life and the market.

Cooper takes a different approach to the study of the biotech sector, focusing on the financialisation of life in the neoliberal economy. Here, she argues, this neoliberal system has a special foundational connection with the emergence of the life sciences sector through the use of speculative capital (Cooper 2008). This study resonates with topics from Foucault’s study of liberal and neoliberal governmentality, and she draws expressly on the Foucauldian concepts of genealogies and biopolitics, but states that she does not wish to engage in their detailed definition (Ibid., 5). Nevertheless, her emphasis on the role of IPRs as economic instruments shows how speculative neoliberal economic relations fundamentally rely on the creation of stable objects for exchange. On the basis of this, the next chapter argues that IP is becoming even more relevant as molecular knowledge’s influence spreads beyond the scientific sector. However, this increasing influence also gives rise to a more contested status of exclusive ownership over this knowledge.

Rouvroy’s analysis of *Human Genes and Neoliberal Governance* (2008) explores the connection between genetic and economic reductionism, and what she terms the “disciplining effects” of genetic knowledge on the level of the individual. These insights tease out interesting aspects of the connection between governmentality and molecular conceptions of life, which will also be explored in the

next chapter. She focuses on IP as part of the convergence between economic and genetic reductionism, and argues that patentability promotes reductionism (Ibid., 41). However, the *Myriad* judgement and problem of patenting “information” partially contradict this correlation. Chapter IV shows that the IP regime’s turn to an informational-genetic reductionist vision of life endangered the patentability of genetic sequences. Interestingly, the influence of the ‘disciplining’ effects of genetic knowledge on the individual can also produce increased demands for access to knowledge – and thus give rise to claims against the exclusive ownership of such knowledge. The convergence between economic and genetic reductionism thus gives rise to an intensified political dimension of molecular conceptions of life, in which IPRs play more roles than a unidirectional tool for the formation of commodities.

Conclusion

This chapter surveyed the existing critical literature on the role of IPRs in human genetic materials, and traced a recent emergence of studies turning to the wider implications of the genetic conception of life beyond the life sciences/ biotech sector. In this it found that studies focusing specifically on IP were critical predominantly of IP’s role in promoting the ‘commodification’ of life. Arguments focus either on a post-colonial critique of international system facilitating biopiracy, or on a more libertarian critique of IP’s legitimacy in enclosing the shared ‘commons’ of humankind. This focus on economic systems of exchange has been criticized for neglecting other social relations of exchange, which are particularly effective in the area of tissue donation and health. However, this debate failed to engage with the social influence of genetic knowledge beyond a discussion of more appropriate boundaries of property. More recently, analyses of the turn to molecular biology began using Foucauldian concepts of governmentality and biopolitics in order to emphasise the fundamental influence of genetic conceptions of life on processes of identity formation of individuals and their understanding of responsibility in medical terms. The coming chapters analyse IP’s treatment of genetic materials as located within this wider “problematization” of life (Foucault 1994, 114) in molecular terms, and argue that IP here contributes to the governing of tensions arising from the formation of new modes of subjectification and between competing forms of knowledge over life. This understanding of IP’s role in the governing of genetic life

highlights the relevance of law within governmentality's management of biopolitical challenges, and explores IP's role as a "tactics" for governing on the intersection of life and the market.

Chapter III Intellectual property as a tactics of government at the intersection of life and the economy

“[...] I think that you are completely free to do what you like with what I am saying. These are suggestions for research, ideas, schemata, outlines, instruments; do what you like with them. Ultimately, what you do with them both concerns me and is none of my business.” (Foucault 1997, 2)

“The [...] perhaps most revealing aspect of liberalism is the relation between liberalism and law.” (Dean 2010, 140)

This chapter develops a different analysis of IP's problematic relation to life. Rather than focusing on the commodification of life by means of patents, it puts forward a perspective that foregrounds a comprehensive “problematization” of molecular life for governing (Foucault 1994, 114) – understood here as the ‘genetic *dispositif*’. This “analytic” of power (Dillon and Lobo-Guerrero 2008, 272) allows for closer scrutiny of the complex dynamics and political aims at work at IP's intersection with life – conceived of as information derived from human genetic materials. However, Foucault's concepts of biopolitical priorities pursued in a new art of governing (governmentality) need to be re-read to reflect the challenge of governing an informational-genetic conception of life (understood here as a genetic *dispositif*), which is giving rise to intensified contestations of IP's increasingly significant role within a neoliberal economy. Both these modalities show how a previously “mundane” (N. Rose and Valverde 2010, 546) field of rather technical law such as IP suddenly became centrally involved in a way of governing and also in the operation of a significant sector of the neoliberal economy. At the intersection of life and the market, this field of law is increasingly forced to operate as a “tactics” of government (Foucault 2000, 211), negotiating tensions and challenges while still enabling the operation of the bioeconomy relying on IPRs.

Besides adapting Foucault's analyses to a molecularised view of life and a neoliberal economy, this reading also further refines the understanding of the function

of law within Foucault's concept of governmentality, and argues that because of these intensifications, law becomes a central site of governing within governmentality, resolving tensions while continuing to govern *for* the market. This chapter sets out the analysis of the governing of life in Foucault's concepts of governmentality and biopolitics, and then shows how these need to be adapted to the influence of the informational-genetic conception of life (Dillon and Lobo-Guerrero 2009) and the particular connection between the neoliberal economy and the biotech sector (Cooper 2008; Thacker 2005a). It argues that the concept of the 'gene' has been particularly effective in connecting knowledge of the individual with that of the population in a genetic *dispositif*, and in facilitating an easier inclusion of this informational-genetic view of life into an economic system that relies on stable IP rules for generating economic value from future potentialities of life. This analytical perspective shows how IPRs are becoming a central consideration for the function of the economy but are also increasingly challenged because of their simultaneously increasing relevance for the governing of individuals and populations. After setting out the particular analytical framework for the study of IP's role in the problematization of life (adapting Rabinow & Rose's work on biopower 2006), the chapter then argues that at the intersection of life and the market, IPRs are increasingly operating as a "tactics" of government in reconciling these two at times divergent priorities.

1. The problematization of 'life' in a new way of governing

In his books and lectures at the end of seventies, Foucault famously argued that from the seventeenth century onwards, "the ancient right to *take* life or *let* live was replaced by a power to *foster* life or *disallow* it to the point of death" (Foucault 1978, 138, emphases in original). He traced the increasing turn of the art of governing towards the life of populations in a fostering or productive⁹ manner, and charted the historical emergence of this logic in the development of the liberal system and the later neoliberal variant. This 'productive' way of governing stood in opposition to the

⁹ This notion of the productive character of neoliberal governmentality is used as a reminder of the turn away from restrictive and prohibitive practices of governing, towards the provision and normalisation of 'good' practices promoting the life and health of a population. It refers to processes of "active differentiation, regulated self-responsibility, and depoliticized autonomy" (McNay 2009, 62) on the basis of a "new somatic ethics" (N. Rose 2008a; N. Rose 2007a, 26). This productive nature facilitates new strategies for political intervention, creates new modes of subjectification, and reinforces the prevalence of a particular truth discourse on life, as the continuing success of the genetic-reductivist version of genomics in comparison to other accounts shows (see next chapter).

restrictive character of sovereign power exercises, which mainly governed by directly imposing punishments for undesirable behaviour. In this process of change, medical and technical knowledges became crucial sources of information for the formulation of governmental strategies. However, this connection entailed a wider “problematization” of conceptions of life, meaning that it gave rise to “the development of a domain of acts, practices, and thoughts that [...] pose problems for politics” (Foucault 1994, 114): life became a political problem. This chapter argues that the relevance of knowledge over life for questions of governing was even more intensified by the emergence of the informationalised and molecularised vision of life. Laws establishing property over these forms of knowledge gained in significance as a result. A better understanding of the changing role of law in a new way of governing thus can highlight intellectual property’s complex engagement with a politics produced by a molecular conception of life.

1.1. Governmentality’s productive relation to ‘life’

Foucault’s fragmentary conceptions of governmentality and biopolitics were based on his analysis of the emerging bureaucratic state apparatus of the 18th century, in which advances in medical science and statistical method coalesced with newly centralised state power. This opened up an entirely new field of political intervention: the population. Foucault argues that the new emphasis on the life of populations, a biopolitics, was part of the emergence of a new art of governing, or “governmentality”, which “has as its purpose not the act of government itself, but the welfare of the population, the improvement of its condition, the increase of its wealth”, which is achieved by means of “[direct] large-scale campaigns” or “[indirect] techniques that will make possible, without the full awareness of the people, the stimulation of birthrates, the directing of the flow of population into certain regions and activities” (Foucault 2000, 217; see also Dean 2010; 2013; N. Rose, O’Malley, and Valverde 2006; Lemke 2007; 2011; Elbe 2005; 2009; T. C. Campbell and Sitze 2013; Muhle 2008; N. Rose 2007b; Rabinow and Rose 2006; Dillon and Reid 2001; 2009; Dillon and Lobo-Guerrero 2008; 2009). In this sense, the art of governing sought to put into place parameters that would ‘produce’ improved conditions of life – in a sense, “produce what you need to be free” (Foucault 2008, 63). But this very need to produce the conditions of freedom “entails the establishment of limitations, controls, forms of coercion, and obligations” (Ibid., 64).

Direct interventions consisted for example of the developments of new norms for the construction of cities (Foucault 2007, 18), and indirect interventions consisted of new social norms for the individual's responsible and healthy conduct, enforced not centrally, but in a decentralised "capillary" manner (Foucault 1977, 198).

In this new art of governing, the population is directly and indirectly incited to contribute to the improvement of two different yet increasingly intertwined priorities of governing – life and the market. Instead of intervening with direct force, government rather "conducts the conduct of men" indirectly (Foucault 2008, 186), thus puts into place arrangements that "govern at a distance" – for example through the intermediary function of the expert translating the goals of government to the individual and incorporating individual demands into advice to policy makers (Miller and Rose 1992; 2008). The epistemological conditions according to which conduct is judged to be appropriate, or conducive to the "right disposition of things" (Foucault 2000, 208), are influenced by the notion of an "economical way of governing", in which the "constitution of knowledge [*savoir*] of government is absolutely inseparable from that of knowledge of all the processes related to population in its larger sense – that is, what we now call the economy" (Ibid., 217).

This meaning of the term economy¹⁰ encompasses and presupposes the production of different knowledges as basis for appropriate actions of government. Rose, O'Malley & Valverde point out that "[t]o govern [...] it was necessary to know that which was to be governed, and to govern in the light of that knowledge" (2006, 87). Scientific knowledge of the 'nature' of life became increasingly important, as biopolitical priorities began to determine the "border between the too much and too little [...]" of governmental intervention according to "the nature of things" (Foucault 2008, 19). 'Economic' governing thus had to adapt to appear appropriate according to the scientific knowledges of life. However, knowledge "of all the processes related to population in its larger sense" (Foucault 2000, 217) also enabled an evaluation of potential strategies according to "the principle of the self-limitation of government" (Foucault 2008, 19). The neoliberal economic critique thus poses a limit to biopolitical strategies emphasising the welfare of populations, as governmentality "will not be content to derive norms of the optimal conditions for the population to

¹⁰ 'Economy' is understood in a wider meaning: "To govern a state will mean, therefore, to apply economy, to set up an economy at the level of the entire state, which means exercising toward its inhabitants, and the wealth and behavior of each and all, a form of surveillance and control as attentive as that of the head of a family over his household and his goods" (Foucault 2000, 207).

expand and prosper. It will balance these considerations against another set of norms [...] derived from the delicate, unstable disequilibrium between the population and the resources necessary for its maintenance” (Dean 2010, 137). In this sense, Dean points out that “[a]t one level, liberalism is a version of bio-politics; at another, it exists in a kind of permanent tension with bio-political imperatives” (Ibid., 133). The two priorities of governmentality – life and the market – are exerting challenges to and act as limiting critiques on each other (Ibid., 120).

The ‘market’ acts as a central site of this economic critique of governance, acting as “a site of veridiction, [...] a site of verification-falsification for governmental practice” (Foucault 2008, 32). Here, an economic calculus replaces the (moral) determination of true and false made by the previous “juridico-disciplinary model” (see for example Foucault 2007, 37 ff.) with “the question of the too much and the too little” of governmental intervention (Foucault 2008, 28). The influence of this calculus on the realisation of biopolitical strategies means that “[population phenomena] are considered as natural phenomena in relation to which one needs to calculate the costs, the required level of expenditure to manage these costs, and the likelihood that the expenditure will achieve the desired ends” (Elbe 2009, 67). This highlights that in governmentality, life is understood in economically contingent ways – and that particular biopolitical strategies are not necessarily primarily beneficial for health as such.¹¹ While a greater priority is placed on the promotion of life and health through governing, any definitions of life are also increasingly understood in terms of economic “cost-benefit” calculations (Ibid.).¹² Furthermore, what is judged to be ‘good’ for the population is also extremely contingent on social context and the value judgements made within this context – which is also the underlying argument of Foucault’s explorations of the foundations of contemporary power structures.

Scientific knowledge of ‘life’ thus became decisive to the determination of appropriate interventions, which were based on the knowledge of the “regularities” within the population (Foucault 2000, 216). The original conception of life of the population arose from the close study of the individual in the institutions of the penal system and the clinic – where individuals were physically re-educated or disciplined

¹¹ As Agamben’s work for example points out, these preoccupations with population health can be far from actually beneficial for the individual (Agamben 1998, further discussion in later section of this chapter).

¹² This simultaneous effect on health policies was brought to my attention by Simon Rushton. For his work on global health and neoliberalism see Rushton & Williams (2012).

into new modes of conduct (see for example Foucault 1963; 1977). This knowledge of the individual was compiled in an “apparatus of writing” and analysed according to a new comparative system “that made possible the measurement of overall phenomena, [...] the calculation of the gaps between individuals, their distribution in a given ‘population’” (1977 Ibid., 190). These observations of the physical body created the notion of the population, and opened up the processes of life to the intervention of politics on the physical level. In this way, the definition of life became “problematized” for questions of governing – resulting in an ongoing process of definition and contestation that continues to raise new questions for political interventions. Foucault highlights similar ongoing problematizations concerning the issue of madness, sexuality, and crime and punishment, and argues that these can never be resolved “completely” by government (Foucault 1994, 114).

Governmental interventions in the area of life and the body comprise an individualizing and a collectivizing method (Muhle 2008, 27; Foucault 1978, 139). Two series of power technologies operate “in a double mechanism” on the human body: as a “thorough administration of the individual *body as machine*” in the case of “the body-organism-discipline-institutions series” of “anatomo-politics”, and in “a planning of life as a *biological process* according to calculations” in the case of the “population-biological processes-regulatory mechanisms-State” series of “biopolitics” (Muhle 2008, 27 emphasis in original, my translation; Foucault 1997, 250; originally taken from Foucault 1978, 139). Importantly, both levels remain tied to the new logic of “power that has a positive relation to life, that fosters and protects it” (Muhle 2008, 27, my translation).

It is argued below that these methods, which address either the body of the individual or the biological processes of the population, are intensified by the new molecular ‘truth’ about life. The genetic code of the individual contains information that can only be interpreted with reference to databases of knowledge compiled from large numbers of people – thus with reference to a new “apparatus of writing” in the language of DNA – but address the body of the individual on the sub-cellular, molecular level, which goes beyond Foucault’s original analysis of the disciplined bodies of soldiers. It is argued that genetic knowledge thus has a more profound effect on the conduct of the individual and also on interventions on the collective body of the population, producing new norms for behaviour but also new problems for

governing in the process. Before this chapter turns to this reinterpretation of Foucault's ideas in the light of the influence of the genetic *dispositif*, it first sets out how 'governmentalisation' manages tensions in an unfolding process of accommodation, and briefly explores the limits of this productive way of governing.

1.2. Accommodating tensions between life and the market in a process of governmentalisation

In Foucault's work, the notion of biopolitical strategies aimed at the life and health of population is presented as a priority that unfolds over time and that increasingly affects the more traditional modes of power exercise (sovereign and disciplinary) – making it more productive over time (Dean 2010, 125; Foucault 2000). Elbe sets out the precise correlation of the three levels of exercise of power contained in Foucault's analyses – sovereign, disciplinary, biopolitical (or more broadly: governmental) – and points out that "they do not stand on an equal footing. Schematically, it is the newer, governmental economy of power that dominates" (Elbe 2009, 70). As already set out before, this governmental economy of power judges the appropriateness of governmental intervention with reference to the market as a "site for veridiction" (Foucault 2008, 32), relying on technical knowledge of the "nature of things", and with an increasing emphasis on biopolitical priorities. The governmental 'productive' way of governing here promotes biopolitical priorities, but also acts as a limiting economic critique on these strategies.

Setting this new economy of power as a point of reference for the other two power exercises resulted in a process of reorganisation and adaptation of the other modes of power exercises (sovereign, disciplinary). This process of reorganisation takes place in a "double movement":

"On the one hand, it saw the development of new forms of governmental mechanisms of political rule that managed the welfare of populations explicitly *at the level of population*. On the other hand, it also involved increasingly redirecting older forms of sovereign and disciplinary power in such a way that they now explicitly contributed to this governmental goal of enhancing the welfare of populations." (Elbe 2009, 71, emphasis in original)

The redirection of older forms of power according to this new goal resulted in a process of “governmentalisation” of previously predominantly sovereign regimes such as law (see also N. Rose and Valverde 2010, 543; and Dean 2010, 133 on this process of reorganisation, especially with regards to law). The implications of this process especially for the field of IP law are explored at the end of this chapter and throughout this thesis, in a specific re-reading of Foucault’s understanding of law that emphasizes law’s new role as “tactics” that ensures the right disposition of things within the new art of governing (Foucault 2000, 211). In this role, law increasingly negotiates tensions between priorities of governmentality, accommodating the pressure to be conducive to life within a legal framework that continues to govern for a market. Law – and especially IP law – thus responds to and negotiates tensions arising from the problematization of life within the existing economic legal framework.

In this context, the role of IP can be re-read as contributing to the governing of life, which allows for example for a different perspective on statements made by representatives of international organisations emphasising the fundamental compatibility of health concerns and IP (see WHO, WIPO, and WTO 2013). Such statements and programmes seeking to reconcile IPRs with public health can now be understood as an accommodation or “constant adaptation of the legal order to scientific discoveries, to the progress of economic organization and technique, [...] and to the requirements of contemporary consciousness” (Foucault 2008, 161). In this sense, these statements on IP can be understood as a product of tensions between the aim of fostering the life of populations and the normalisation of knowledge over life for their economic circulation. As the next chapters point out, at this intersection IP’s role goes beyond the sheer commodification of life, with IPRs exerting normalising and economic powers on the accepted scientific conception of life.

This governmental accommodation of challenges in the name of life can be traced in other ways. Elbe points out that “biopower [...] [was] not merely deployed downwards from the state into society, but [was] consentingly invoked by many social groups [...]. The health of all, he noted, became a priority of all” (Elbe 2005, 407). As subjects were increasingly “encouraged to view [...] lives and identities as a type of enterprise” (McNay 2009, 56), they began to be actively engaged in generating knowledge about their body. As a result, “active patients” (N. Rose 2007a,

11) began to demand access to genetic knowledge about their own life and health, thus challenging the exclusivity of the IP system in a bid to improve their own condition – highlighting the radical potential of biopolitical challenges. In responding to these challenges demanding participation in the bioeconomy, the IP regime comes under pressure to ‘governmentalise’, and contributes to the management of the political problem of life as a tactics of government.

1.3. The limits of productive biopolitics

The notion of a productive way of governing life in a new governmentality has given rise to a variety of critical studies, which interpret Foucault’s work in different ways (see for example Esposito 2008; T. C. Campbell 2011; Clough and Willse 2011; Debrix and Barder 2012; see also overview in Lemke 2007, 9). Not all emphasise governing through the conduct of conduct and conditions of productiveness which “[seek to] increase the means of subsistence, to augment the wealth, strength and greatness of the state, to increase the happiness and prosperity of its inhabitants, and to multiply their numbers” (Dean 2010, 125). This section briefly outlines the difference between an emphasis on the production of the conditions of freedom and the study of biopower at its limits, where the distinctions between sovereign and governmental power exercises are blurred.

Agamben presents a reading of biopolitics that is deeply connected to considerations of (state) sovereignty, looking at the “hidden point of intersection between the juridico-institutional and the biopolitical models of power” (Agamben 1998, 6). In contrast to Foucault’s work, in Agamben’s interpretation “the production of a biopolitical body is the original activity of sovereign power”, which places this connection between biopolitics and sovereign power at the heart of “Western politics”, in which “the inclusion of *zoē* in the *polis* (...) is, in itself, absolutely ancient” (Ibid., 6 and 9). This entails a “correction” (Ibid., 9) of Foucault’s understanding of the emergence of biopolitics as a marker for modern politics and reconceptualises biopolitics as a foundational element of state power. Agamben’s analysis focuses on the most “exemplary places of modern biopolitics: the concentration camp and the structure of the great totalitarian states of the twentieth century” (Ibid., 4).

Lemke argues that as Agamben’s account fails to acknowledge “that biopolitics is, at its heart, a political economy of life, his [Agamben’s] analysis

remains tied to sovereign power and blind towards all those mechanisms, which operate below or beyond the law” (Lemke 2007, 80).¹³ Similarly Fassin points out that Foucault was not concerned primarily with ontological questions of *bios* and *zoē*, but “rather [with] the way in which impersonal ‘living beings’ were turned into populations and individuals, how governmentality and subjectification shaped our modern vision of the world and of humanity” (Fassin 2009, 47; in a similar vein Lazzarato 2002, 101; Meloni 2010). Furthermore, in the context of his analysis of neoliberalism, Foucault cautioned against neoliberal “state phobia” and its “inflationary critical currency” which leads “an analysis of social security and the administrative apparatus [...] to the analysis of concentration camps” (Foucault 2008, 187f.). A similar caution should be made against focusing critiques exclusively on the extremes of biopolitical strategies at the expense of an analysis of the productive operation of power within the neoliberal system.

However, important analyses of the operation of power at the limits of biopolitics have drawn attention to the conditions of possibility on which the concept of biopolitics is founded. Selmeczi shows that the biopolitical fostering of some parts of populations always also entails an abandonment of others – which are not counted amongst the numbers making up the respective population (Selmeczi 2009). Furthermore, analyses emphasise the politics of death at the limits of biopolitics (for thanatopolitics, or the “politics of death”, see Foucault 1997, 254ff.; Clough and Willse 2011; Ailio 2013; evaluated in detail by T. C. Campbell 2011; Esposito 2008, 110ff.; T. C. Campbell and Sitze 2013) showing how the securing of the life of the population justifies death and destruction at its limits, and as part of its exercise. The promotion of life in the liberal system produces life in a way that necessarily also depends on death – as shown for example in the Obama administration’s condemnation of torture methods, which however was accompanied by a normalisation of coercive practices and increased reliance on drone strikes (see Clough and Willse 2011, 2; see also Dillon and Reid 2009).

Godoy’s analysis *Of Medicines and Markets* suggests a particular connection between IP and biopower in its concluding remarks on “intellectual property and

¹³ In this critique, Lemke does not question Agamben’s approach to law, which focuses on law as sovereign power in an echo of Carl Schmitt’s ideas, and in an Austinian sense, where its characterising feature is primarily that it is *in force*, rendering the content of the law insignificant (Agamben 1998, 51). In opposition to this understanding of law, this chapter argues that the function of law changes in a governmental system.

human rights in the free trade era”, arguing: “It is difficult to imagine a more quintessential example of biopower than intellectual property” (Godoy 2013, 141). She does not elaborate on this statement in much greater detail, except for finding in contemporary Western politics “it become[s] necessary, in the name of prosperity and progress, to sign laws condemning the poor to lack medicines”, which “is the genius of biopower; it permeates false divisions between private and public, [...] determining who lives and who dies, all in the name of scientific advancement and the rule of law” (Ibid., 140). Explicitly drawing on Agamben’s reading of Foucault’s Biopower (and that of Hardt and Negri 2000), she thus equates IP’s role in determining the price of medicines with the power to decide “who lives and who dies” (Godoy 2013, 140, Footnote 10).

Godoy’s brief statements thus find the globally enforced system of minimum standards of IP protection enshrined in TRIPS to be implicated in a more sovereign exercise of biopower, instrumental in drawing the dividing line between those that “count” and those that are left “abandoned” (Selmeczi 2009). In contrast, Pottage’s succinct reflections on IP find “the patent process [...] almost the paradigmatic example of a bio-political programme”, which “[does] not identify [itself] with one side of the distinction between norm and nature, rather [it] treat[s] the distinction itself as a provisional programme which serves to govern [its] own operation” (Pottage 1998, 746 f.). This interpretation of IP as biopolitical programme emphasises IP’s contingency on changing definitions of ‘truths’, rather than a re-inscription of absolute boundaries. The notion of IP as a biopolitical programme can be interpreted as an earlier statement on the “responsive” function of law (Golder and Fitzpatrick 2009) within governmentality, reflecting “the productive capacity of power” (Lemke 2005, 3). This moves away from a straightforward equation of IP with biopower, and rather begins to explore the interaction of IP with notions of life, where IP re-inscribes boundaries and faces challenges in the name of life.

1.4. IP as global biopower or IPRs as a tactics of government?

The exclusionary and destructive effects of the productive logic of biopolitics are especially noticeable within the IP regime on the international level, as chapter VI of

this thesis argues.¹⁴ Here, the fostering of some populations is taking precedent over that of others, one of the foundational conditions of biopolitical governing according to the critical use of the concept of biopower. However, tensions are emerging at the core of the international neoliberal economy, questioning the effects of the IP regime on the lives and health of disadvantaged parts of the (global) population (see WTO 2001; WTO 2002; CIPIH 2006; CEWG 2012a; WHO, WIPO, and WTO 2013). This thesis traces these emerging contestations and the way in which IP here “engage[s] responsively with exteriority, with an outside made up of resistances and transgressions” (Golder and Fitzpatrick 2009, 56). This does not declare the emergence of a global biopolitics in the manner of Hardt and Negri’s comprehensive *Empire*, in which “a new global form of sovereignty” is ruling “social life in its entirety” in a “paradigmatic form of Biopower” (Hardt and Negri 2000, xii and xv). The analysis rather focuses on tensions within a specific legal regime that operates on the intersection of the economy and genetic conceptions of life – uniquely connecting national jurisdictions with international organisations and standards, and giving rise to debates on the relation of IP and life especially within international organisations at the core of the neoliberal international economy.

This specific focus on a particular legal regime seeks to contribute to recent debates about the defensibility of claims about global governmentality and biopolitics (see Kiersey 2009; Chandler 2010; Rosenow 2009; Kiersey, Weidner, and Rosenow 2010; Selby 2007). Selby for example argues that the “scaling-up” of Foucauldian ideas involves a “double reading”, where “[international political relations] are read first as liberal and, on the strength of this, these global liberal realities are analysed as the products of disciplinary and bio-political power” (Ibid., 334; see also Chandler 2010 for a critique of reaching beyond the liberal state). This, he finds, “support[s] what are in essence reworked and reworded liberal accounts of international politics” (Selby 2007, 334). While “global” versions of governmentality and biopolitics are thus criticised for neglecting “the specificity of the international”, some analyses are however endorsed as “bringing to the fore, the diverse liberal discourses, practices and techniques of international politics” (Ibid., 332).

Instead of putting forward an understanding of ‘global biopolitics’ in general, in response Kiersey emphasises the potential of Foucault’s work on governmentality

¹⁴ The exclusionary function of IP is also explored in the chapter on modes of subjectification engendered by the IP regime’s connection with genetic conceptions of life.

and biopolitics to “address the role of economic ideology in contemporary globalisation” (Kiersey 2009, 365). He argues that Foucault’s recently published lectures in particular can provide an understanding of how “contemporary capitalism relies on the market as a potential vector for the solicitation of specific norms of individual responsibility” (Ibid.). Rosenow furthermore argues that governmentality’s strength in analyses of decentred relations of power radically questions the validity of universal categories such as “the international” (Rosenow 2009, 500). She advocates the analysis of “a particular set of practices at a particular site” rather than being drawn into statements of a universalist nature – and shows how different forms of neoliberalism can be found at different international sites, for example in negotiations at the WTO on the import of genetically modified organisms to the European Community (Ibid., 502 ff.).

This thesis argues for the use of Foucauldian concepts in analyses of specific debates within core organisations at the intersection of the international neoliberal economy and the international administration of health. IP law is particularly unique due to its connection between the international and the national level, with the US exerting an especially strong influence (Sell 2003; Tyfield 2008). It thus has strong connections to the neoliberal variant of the US as described in Foucault’s recently published lectures (Foucault 2008). This US version of neoliberalism connects life and economic relations in a “theory of political economic practices that proposes that human well-being can best be advanced by liberating individual entrepreneurial freedoms and skills within an institutional framework characterized by strong private property rights, free markets, and free trade” (Harvey 2005, 2). But the IP system’s exclusion of large parts of the global population is also strongly reminiscent of Foucault’s statements on the global dimension of the earlier liberal notion of limitless European progress, which made it “necessary to summon around Europe, and for Europe, an increasingly extended market and [...] everything in the world that can be put on the market” (Foucault 2008, 55). In this sense, “[t]he game is in Europe, but the stake is the world” – with “Europe on the one side, with Europeans as the players, and then the world on the other, which will be the stake” (Ibid., 55 and 56).

Thus the IP regime stands uneasily between liberal and neoliberal priorities of governing.¹⁵ The exclusion of large parts of the world's population from any meaningful participation in the making of IP policy, or in the proceeds (be they medicines, knowledge, or profits) asserts a version of 19th century liberalism's "global calculation" of governmentality promoting European and US progress – comparable to Foucault's example of maritime law (Ibid., 55). But the extension of IP law to genetic materials and IP's foundational significance for the raising of speculative capital for the biotech sector (Cooper 2008) increasingly intensify tensions around the ownership of molecular knowledge over life – even on the international level. Importantly, the influence of genetic knowledge reaches far beyond this economic function, as the genetic *dispositif* redefines life, identity, and well-being pervasively. The molecularisation of life thus also further intensifies tensions around IP on genetic materials. The following sections first turn to these two transformations and the pervasive influence of the genetic *dispositif*, and then highlight this *dispositif*'s governmentalising effects on IP law. This generates a framework for analysis that provides a deeper understanding of the changing role of law in a governmental system. The following chapters then illuminate IP's responsive engagement with challenges, and its function as a "tactics" of government in managing emerging tensions and challenges specifically within this international legal regime.

2. Intensifying biopolitics – Two transformations and the gene as a '*dispositif*'

Much has changed since the beginnings of statistical measurements of population phenomena. This section argues that in the light of scientific advances since the discovery of the genetic code, and the formation of a much more institutionalized form of international trade with the WTO, Foucault's original studies have to be adapted to new exigencies raised by an economy of governing based on knowledge of life formed at the molecular-genetic level. The shift to the molecular level of life led to the body being conceived of "on a different scale" (N. Rose 2007b, 44) – which was much more than a mere change of scale in the way that medicine could analyse the processes within the body. Dillon and Lobo-Guerrero argue that this led to the emergence of a "new order of the real", which consisted of two transformations: of the subject and of the integration of life into the economy (Dillon and Lobo-Guerrero

¹⁵ It was strongly contested and considered a tenuous compromise from the very beginning of US liberal politics, as Thomas Jefferson's disparaging comments on IP show (see Boyle 2008, 17 ff.).

2009, 9). This section points out that the transformation of the conception of life intensified the governance of individuals and populations, and argues that it is helpful to conceive of the far-reaching effects and influence of the change to the molecular level by introducing the notion of a genetic *dispositif*. The second transformation of life into value intensified the tensions between the creation of speculative value from life and legal regimes such as IP, which enable this integration. These two transformations, which are particular to the informational-genetic conception of life's relation to the neoliberal economy, problematize the governing of life beyond Foucault's original notion, and can better explain the increasing significance of and controversies around IP law. On the basis of these transformations, this section then introduces a framework of analysis that accounts for these contestations and tensions by interrogating changes on the level of truth, the subject, and emerging strategies for contestation.

2.1. The molecular transformation of life and the emergence of a 'genetic dispositif'

The scientifically accepted definition of the essential content of 'life' has undergone dramatic change since the discovery of the genetic code. The magnitude of this change is akin to that described by Foucault at the emergence of 19th century observational methods in the "clinic", transforming the clinical "gaze" (N. Rose 2007b, 44).¹⁶ This transformation of observation adjusts "[n]ot only the names of diseases, not only the grouping of systems[...]; but the fundamental perceptual codes that were applied to patients' bodies, the field of objects to which observation addressed itself, the surfaces and depths traversed by the doctor's gaze, the whole system of orientation of this gaze" (Foucault 1963, 64). The shift to observations of the molecular-genetic constitution of patients entails a "transformation of what it is to be a living thing" (Dillon and Lobo-Guerrero 2009, 2), and in extension also what it is to be a patient, as shown in the emergence of the "pre-symptomatic ill" based on genetic definitions of risk (Wehling 2011, 234). Now, instead of curing illness, medicine can "transform its basic logic [...] to one engaged in the *molecular re-engineering of life itself*" (Rabinow and Rose 2006, 212; emphasis in original).

¹⁶ Rose points out: "It was a reorganization of the gaze of the life sciences: their institutions, procedures, instruments, spaces of operation, and forms of capitalization" and also "a redefinition of life: life as meaning" (N. Rose 2007b, 44).

This turn also involves a change from a chemical conceptualisation of the body to an informational-genetic one, which has a strong scriptural element: “[c]ontemporary biology has ‘dropped the vocabulary of classical mechanics, physics and chemistry [...] in favor of the vocabulary of linguistics and communication theory. Messages, information, programs, codes, instructions, decoding: these are the new concepts of the life sciences’ [...] If we are to understand life, its message must be decoded before it can be read” (Canguilhem 1994, 316–317; quoted after N. Rose 2007b, 44). In this way, the shift brought about “a redefinition of life: life as meaning” (Ibid., 44) – interpreted as a somatic destiny which gives rise to new rights and responsibilities of the individual (N. Rose 2008a; McNay 2009; Metzl and Kirkland 2010). In a new somatic ethics “[h]uman beings identify and interpret much of their unease in terms of the health, vitality, and morbidity of their bodies; they judge and act upon their soma in their attempts to make themselves not just physically better, but also to make themselves better persons” (N. Rose 2008a, 46). This somatic reinterpretation of identity however also poses a political challenge, as governing has to adjust to new knowledge of the population determined by genetic science, and the demands of (pre-symptomatic) patients made on the basis of new conceptions of well-being and illness.¹⁷

This transformation of “what it is to be a living thing” (Dillon and Lobo-Guerrero 2009, 2) led to an intensification of the problematization of life and thus to an increasing emphasis on strategies for the governmental management of tensions arising around the informational-genetic conception of life – which has a far-reaching influence on the subject and throughout society. It is argued here that this central influence can usefully be subsumed under the notion of a ‘genetic *dispositif*’. As already pointed out above, the study of governmentality shows how the body is governed on two different levels: individual disciplinary anatomo-politics, and biopolitical strategies aimed at the population directly and indirectly. These different levels of power exercise often come together in Foucault’s work as “concrete

¹⁷ However, the reach of this new molecular vision of life is not universal – the new somatic ethic of a ‘genetic’ or ‘biological citizenship’ (N. Rose 2007b) can only emerge in contexts where genetic testing and medical treatment on this basis are widely available (see critique in Braun 2007; Wehling 2011; Raman and Tutton 2010, see also discussion in chapter V and VI). Only against this backdrop are identities reformulated pervasively, and new forms of governing are enforced.

arrangements (*agencements concrets*)” (Foucault 2008, 140; Muhle 2008, 30), or ‘*dispositifs*’¹⁸.

Agamben defines the term *dispositif* as “a heterogeneous set that includes virtually anything, linguistic and non-linguistic, under the same heading: discourses, institutions, buildings, laws, police measures, philosophical propositions, and so on. The apparatus itself is the network that is established between these elements” (Agamben 2009a, 2). He points out that Foucault never defined the term in detail, even though it is central to many of his works on governmentality. Foucault stated: “The apparatus is precisely this: a set of strategies of the relations of forces supporting, and supported by, certain types of knowledge” (quoted after Agamben Ibid.). The “deployment of sexuality” is an example of such a *dispositif* (Foucault 1978, 140, emphasis in original), where “sexuality allows for the accessing of life in both conditionalities, the individual life of the body and the global life of the species”, sexuality being “at the same time essentially individual (...) and essentially global”, and “functioning thus as a political *dispositif*, which connects the individualising techniques of discipline with the globalising mechanisms of regulation” (Muhle 2008, 31, my translation; also Foucault 1977, 149).

This thesis argues that the concept of the gene (and genetic knowledge in general) is ideally situated on the axis between the individual and the population, as a central code that enables the formulation of individual disciplinary actions and collective biopolitical strategies in the name of life. Genetic information gives on the one hand a very individual account of ‘life’, but at the same time the interpretation of its implications in terms of likely illnesses involves a large amount of statistical data gathered on a population or even global level (Rouvroy 2008, 3; Raman and Tutton 2010, 721).¹⁹ Deciphering an individual’s personal genetic code provides knowledge about future risk potentialities that incite individuals to more responsible conduct, and to act on themselves in order to better their condition (N. Rose 2008a; Rouvroy 2008,

¹⁸ Foucault’s idea of the *dispositif* has recently been taken up by an increasing number of scholars, especially in the context of liberalism and security (Agamben 2009a; Bührmann and Schneider 2008; Shapiro 2011; Lemke 2004; Opitz 2011).

¹⁹ Rouvroy notes this “unavoidably collective nature of genetic information”, interpreting it as a “[disruption of] the liberal representations of the modernist sovereign subject” as an isolated individual (2008, 3). This statement only highlights the paradoxical notion of highly individualised accounts of ‘life’ being formed by population-wide knowledge. Understanding these two levels as seamlessly interconnected within the genetic code, or as a genetic *dispositif*, enhances our understanding of the particular success of the molecular vision of life, places it right at the centre of neoliberal governmentality, and gives an indication to the wide reach of the political and cultural impact that this notion has had.

55 ff. - Rouvroy refers to this as the gene's "disciplinary" power). The generation of genetic knowledge on the population level enables the evaluation of the individual sample – but it also provides a valuable dataset of the population's genetic make-up, which can be used for the targeted deployment of biopolitical strategies. Thus this thesis argues that the genetic code can be seen as a *dispositif* in the Foucauldian sense – addressing life in collective and individual "conditionalities". Understanding the genetic *dispositif* as such a power/knowledge apparatus draws attention to its intensifying potential to bring about far-reaching effects and amplify modes of individual and collective governance.

Re-reading the relation between IP and conceptions of life in this context reveals how they are centrally placed at a very significant intersection between increasingly important technical knowledge for governing, and an intensified problematization of life for questions of governing, enhanced by the influence of the genetic *dispositif*. This influences and redefines individual and collective identities, as for example pre-symptomatic patients join interest groups demanding greater control over the direction of research on their condition, and individuals are encouraged to contribute to the formation of profitable ventures such as population biobanks. IPRs thus have to govern the economic use of technical knowledge in a political sphere that is marked by the increasing influence of the informational-genetic conception of life. This growing influence of the genetic *dispositif* however also complicates the function of IPRs. The informational-genetic understanding of DNA has only recently been formally accepted by IP law (in *Assoc. for Molecular Pathology v. Myriad* [2013]), threatening to unsettle IP's economic role as information alone is not patentable (see chapter IV). As IP negotiates tensions between patentability and the normalisation of informational-genetic conceptions of life, it also plays particularly important other roles in a neoliberal economy, as the second transformation of life into value shows.

2.2. The transformation of life into value and the role of IP in a neoliberal economy

The second transformation integrated this genetic account of 'life' into the economy, in "the transformation of life into value, into the form of commodity and capital, which is taking place under the globalization of capital" (Dillon and Lobo-Guerrero 2009, 2). This transformation was aided by the informational paradigm, which made

the genetic code easily transferrable to the economic sphere, in a proliferation of various “bioinformatic artifacts” (Thacker 2005a, 52). Cooper argues that this merging of the life sciences and the economy was further intensified by their “common ambition to overcome the ecological and economic limits to growth associated with the end of industrial production, through a speculative invention of the future” (Cooper 2008, 11). This unlocking of speculative value, she points out, is part of the neoliberal financialization of life - which does “not so much [seek] the generalized commodification of daily life” but in a departure from the previous liberal model rather “installs speculation at the very core of production” (Ibid.).

Cooper highlights IP’s central position in this neoliberal financialisation of life using the example of the contested patentability of pluripotent stem cells, which contain the potential of developing into virtually any cell in the human body. In contrast to the emphasis on the commodification of life, she argues that the patenting of stem cells does not aim at establishing “an exchangeable equivalent” value, but rather lays claim to “a self-regenerative surplus value, a biological promise whose future self-valorizations cannot be predetermined or calculated in advance” (Ibid., 148). This turns “biological life [...] into speculative surplus value” (Ibid.), and results in an unprecedented preoccupation of IP law with “the ontological problem of our humanness” (Ibid., 146). In this neoliberal economy of speculative surplus value derived from biological life, the field of IP law has emerged as a central site establishing the control of intellectual (potential) value – life’s “future powers of emergence” (Ibid., 190). However, while highlighting this particular relevance of IP for the neoliberal economy, Cooper does not question the relation of IPRs to different genetic conceptions of life in more detail. As IP law becomes fundamentally involved with defining the essence of “humanness” it also normalises predictable informational-genetic conceptions of life at the expense of complexity and environmental influence (see chapter IV). Thus IP contributes to the governing of knowledge and manages tensions between complexity and control in a neoliberal economy.

This thesis argues that the emphasis on IPRs and their role in the appropriation of surplus potential value renders them central to the question of the governing of life, where they for example accommodate the challenge of genetic complexity while they also ensure the continued function of economic exchange. The following chapters approach the question of the governing of genetic life on three different levels in a

framework that conceptualises this confrontation as an encounter with biopower. Of course, this thesis does not seek to argue that IPRs are not generating commodities for trade, but finds that the problem with IP's relation to life goes far beyond this function, and rather involves questions of the normalisation of certain types of knowledge and managing challenges to the exclusive power over this knowledge. This analysis re-evaluates the role of law at the intersection of life and the economy using the understanding of an increasing governmentalisation of IP law. The conceptual framework for analysis traces tensions between IP and the productive capacity of life in three different ways. The use of this perspective can show how tensions created by a neoliberal economy of life are met by a changed "responsive" role of law within neoliberal governmentality, in which a deregulation of economy paradoxically caused "regulatory activities of government [to become] hyperactive" (Martin 2011, 271; see last section below).

2.3. Analysing IP's role(s) in governing 'life' - A conceptual framework

The two transformations of life into an informational-genetic code and of life into value thus have resulted in IPRs' increased importance for the economic circulation of life, but also rendered it more central to questions of the governing of life. Both these developments can explain increasing challenges to IP in the name of life, as the growing influence of knowledge over life leads to contestations over its control by 'genetic' subjects, while IP's role in the financialisation of life continues to increase the economic relevance of this control. IPRs have thus become a central site of negotiation of tensions in what Rose terms new "economies of vitality", where "biopolitics [have] become inextricably intertwined with bioeconomics" (N. Rose 2007b, 6). The question of the government of life thus intensifies not only the relevance of genetic knowledge of the individual and the population, but its relation to the economy. This gives rise to a novel political field that traverses traditional divisions between biology and economy, and between the national and the international as "transnational flows of knowledge, cells, tissues and intellectual property are coupled with local intensifications and regulated by supranational institutions" (Rabinow and Rose 2006, 215). IPRs are a central "power relation" at the intersection of this emerging transnational "economy of vitality", and the genetic

dispositif, and this thesis argues that their function at this intersection needs urgent attention beyond the focus on their role in commodification.

The roles of IPRs within this economy and the challenges they are encountering will be analysed in the coming three chapters, which argue that in their confrontation with genetic conceptions of life, IPRs are undergoing a process of governmentalisation in which they are becoming a tactics of government. The chapters investigate IPRs' exposure to the problematization of life on three separate yet connected levels, in an "analytic", which seeks to "[detail] the operational logics, forces and dynamics at play in a specific configuration of power relations" (Dillon and Lobo-Guerrero 2008, 272). IPRs are here treated as "epistemic objects"²⁰ that are "constituted through practices of power" (Lobo-Guerrero 2011, 9). They for example reflect struggles between scientific truth discourses, and are involved in and challenged by the formation of new responsibilities and duties.

This thesis interrogates contestations of IP as an exposure to biopower and its productive logic as a part of governmentality. A conceptual framework for analysis accounts for the ways in which biopower problematizes life for questions of governing, following Rabinow and Rose's rigorous examination of biopower's relation to a neoliberal economic context, specifically with regards to informational-genetic conceptions of life and their productive capacity. They point out that at its basic level, the governing of life (or the engagement with biopower) encompasses a "configuration of knowledge, power and subjectivity" (Rabinow and Rose 2006, 212). In a definition of biopower that is "not trans-historical or metaphoric, but precisely grounded in historical, or genealogical, analysis" (Ibid., 199), they state:

"the concept of biopower designates a plane of actuality that must include, at a minimum, the following elements: [1] One or more truth discourses about the 'vital' character of living human beings, and an array of authorities considered competent to speak that truth. [...] [2] Strategies for intervention upon collective existence in the name of life and health, initially addressed to populations that may or may not be territorialized upon the nation [...] [3] Modes of subjectification,

²⁰ Lobo-Guerrero adapts the term "epistemic objects" from Rheinberger's original use, and deploys it in an analysis of insurance. Lobo-Guerrero argues that insurance also seeks to "capitalize life", and runs into significant problems in the "molecular age" (Lobo-Guerrero 2011, 38 and 53).

through which individuals are brought to work on themselves [...] by means of practices of the self, in the name of their own life or health [...]” (Ibid., 197).

This thesis uses this constellation of elements involved in the exercise of biopower as a framework structuring the analysis of the conflicts and contestations of IP’s relation to life in order to grasp the productive capacity of the political sphere surrounding genetic conceptions of life. The following chapters analyse the problematization of life and the role of IP in the governing of life on the level of truth discourses, modes of subjectification, and strategies for intervention.

This thesis does not argue that this analysis will show that the IPR apparatus changing beyond recognition or undergoing a radical overhaul – it rather focuses on a persistent area of debates about legitimacy and reform of IPRs’ relation to life and health. Challenges giving rise to small changes and surprising developments that are not explained by the question of ‘commodification’ can thus be reinterpreted as part of a process of accommodation to demands produced by a new point of reference: molecular life. IP’s involvement in the definition of truth over life shows how the IP system attempts to accommodate the overwhelming influence of the informational-genetic dispositif while still ensuring its patentability, in an otherwise inexplicable US decision against the patenting of certain information derived from human genetic sequences (*Assoc. for Molecular Pathology v. Myriad* [2013], chapter IV). The relation of IP to the subject can be analysed with reference to demands incited by a new “somatic ethics” (N. Rose 2008a) or notions of “biological citizenship” based on genetic conceptions of life (N. Rose 2007b). These are shown to contest options for participation in the bioeconomy but also to work alongside the IP regime, as subjects are encouraged to voluntarily contribute to research but are prevented by means of IP transfer from any further participation in the use of results (chapter V). On the international level, the question of participation appears even more starkly, but the exclusionary function of the IP apparatus is also increasingly challenged by means of the right to health and within Global Health agendas. These new strategies for intervention are explored in contestation of IP’s centrality to an economy deriving value from life from different peoples across the globe (chapter VI).

Thus, while there are of course many ways in which IPRs are still representative of interests of sovereign power and enforced by means of disciplinary power, it is shown that they have several roles to play – and that these roles are undergoing change as they are ever more centrally involved in the governing of life. The last section of this chapter explores in more detail how an understanding of the productive capacity of a political sphere of life can trace changes in the previously entirely sovereign apparatus of law. This understanding of the governmentalisation of law departs from some conceptions of law in Foucault's work, and advances the analysis of law's function in governmentality by arguing that its operation as a "norm" (Ewald 2010, 146) entails it becoming a "tactics" (Foucault 2000, 211; Odysseos 2010, 755; Sokhi-Bulley 2013) of government, ensuring the right disposition of things – especially at the intersection of life and the economy.

3. The Governmentalisation of Law

The relevance of law and legal forms for Foucault's concepts has been the source of much debate. While some regard Foucault as generally dismissive of the role of law for the processes he was setting out (Hunt and Wickham 1994), others (Ewald 2010; N. Rose and Valverde 2010; Golder and Fitzpatrick 2009; 2010) have formed a more detailed account of the various roles of law that can be discerned in Foucault's work. This section further refines previous conceptions of law within governmentality, arguing that the turn into a "norm" entails a tactical process of accommodation between different priorities, carried out in the field of technical forms of law. Previous understandings of law within Foucault's work focused either on it as part of the sovereign apparatus, a "mask" (Foucault 1977, 222), or on Foucault's later conflicted accounts of the special nature of human rights. However, it is argued here that recent publications of Foucault's lectures enabled a re-evaluation of the role of law in governmentality, unearthing law's central part in the establishment of a "economic-juridical order" in which "[t]he juridical gives form to the economic, and the economic would not be what it is without the juridical" (2008, 163). This illuminates Foucault's earlier statement on law operating increasingly as a "tactics" of government (Foucault 2000, 211; 2007, 99), showing that law tactically resolves the need to govern for the market (Foucault 2008, 121) within "a technology of power centered on life" (Foucault 1978, 144). This understanding of the governmentalisation

of law can then be used in the analysis of IP's "responsive" engagement (Golder and Fitzpatrick 2009, 56) with the genetic dispositif.

3.1. *Dismissing Law(s)?*

On first glance, Foucault seems to generally dismiss studies of certain types or forms of law, or jurisprudence, and devotes large parts of his argument to a deconstruction of its relevance. Law is presented as mostly a legal-philosophical justification for the establishment of sovereign power²¹: "the essential role of the theory of right has been to establish the legitimacy of power; the major or central problem around which the theory of right is organized is the problem of sovereignty" (Foucault 1997, 26). These statements serve both on the one hand to show *how far* legal arguments and structure are imbued with considerations of power, but also on the other hand to then dismiss forms of law as a possibly fruitful site of investigation of change. Law's legitimacy is not addressed by Foucault, in fact, he states: "Right must, I think, be viewed not in terms of a legitimacy that has to be established, but in terms of the procedures of subjugation it implements" (Ibid., 27). This clearly equates law with sovereign and disciplinary power exercises only.

These dismissive statements are also repeated in the context of the concept of biopower – but here a change from law towards the *norm* is set out:

"Another consequence of this development of bio-power was the growing importance assumed by the action of the norm, at the expense of the juridical system of the law. Law cannot help but but [*sic.*] be armed, and its arm, *par excellence*, is death; [...] I do not mean to say that the law fades into the background or that the institutions of justice tend to disappear, but rather that the law operates more and more as a norm, and that the judicial institution is increasingly incorporated into a continuum of apparatuses (medical, administrative, and so on) whose functions are for the most part regulatory. A normalizing society is the historical outcome of a technology of power centered on life. We have entered a phase of juridical regression [...] we should not be deceived

²¹ "In Western societies, the elaboration of juridical thought has essentially centered around royal power ever since the Middle Ages" (Foucault 1997, 25).

by all the Constitutions framed throughout the world since the French Revolution, the Codes written and revised, a whole continual and clamorous legislative activity: these were the forms that made an essentially normalizing power acceptable.” (Foucault 1978, 144, emphasis in original)²²

This passage reveals a very particular understanding of law as opposed to the ‘norm’: Law is most clearly understood as a system that enforces the will of a (17th century) sovereign with absolute force, subjugating the individual through punishment. There is a clear distinction being made between this “juridical system of law” and “the norm”, which is highly instrumental in the establishment of a normalizing society. The norm is thus marked as the new form of law within governmentality.

Despite this apparently clear dichotomy of the law and the norm, Foucault employed several different understandings of legal forms in an at times ambiguous fashion. For example, the passage quoted above hints at the role that human rights and constitutions may have played in the establishment of this society: a trade-off at best, and a smoke-screen at worst. But in later references to “absolute rights” (Keenan 2010, 506; see also Golder 2011; 2013; Whyte 2012; Patton 2005), Foucault is decidedly more in favour of human rights, and attributes them with a certain potential for resistance to existing arrangements – so for example in “a new human rights initiative in defense of Vietnamese boat people” or in defence of “Spanish militants condemned to death in Franco’s court” (Keenan 2010, 503 and 505, originally published in 1997). Foucault’s speech on human rights at the UN argued in favour of “an international citizenry, which has its rights [...] and promises to rise up against every abuse of power”, commissioned by “[n]o one. And that is precisely what establishes our right” (quoted after Keenan Ibid., 504; also reproduced in Foucault 2000, 474). These changes further complicate Foucault’s notion of rights – even if this particular version of human rights is bracketed as a special case.

Hunt and Wickham have put forward the view that “Foucault is concerned with law only illustratively” and that “the most distinctive features of Foucault’s account of the historical emergence of modernity led him to present a view which can be aptly summarised as the *expulsion of law from modernity*” (Hunt and Wickham

²² Parts of this passage are quoted widely within accounts of Foucault’s attitude towards law: see for example Rose & Valverde (2010); Tadros (2010); Ewald (2010); Hunt (2010).

1994, 41 and 56, emphasis added). Other scholars have challenged this “expulsion thesis” and have instead focused on an interpretation of Foucault’s statements based on a more differentiated understanding of the legal domain, looking beyond criminal and constitutional law (Golder and Fitzpatrick 2009, 12).

In his assessment of Foucault’s concept of law, Tadros finds “[t]he term juridical [...] refers to the *conception of power relations* which one might call Austinian” (Tadros 2010, 150, originally published 1998, emphasis in original). John Austin famously admitted only those forms of law to be law that are backed up with real powers of enforcement or punishment through a sovereign (Austin 1954). Thus, in Austin’s understanding, almost all of international law is not actually law, as it cannot be enforced. This is also commonly referred to as the “Austinian Handicap” (for an extensive discussion see for example Barker 2000, 14 ff.). This alignment of the concept of the juridical with this very sovereign – and highly controversial – conception of law limits the area that could be termed ‘juridical’ to such examples as criminal law, which are directly enforceable by the state apparatus and the prison system – an area that is by no means representative of the whole of what is commonly seen as law. Other areas of law, which are closer to the regulatory apparatus of norms or normalization, cannot be equally dismissed as irrelevant emanations or sheer disguises of sovereign power.

Following this interpretation of Foucault’s notion of law allows Ewald to reverse the claim of “a phase of juridical regression”, shifting the emphasis of interpretation of the notorious passage quoted above towards the recognition that “normalization tends to be accompanied by an astonishing proliferation of legislation. Practically speaking, legislators never expressed themselves as freely or as extensively as in the age of bio-power” (Ewald 2010, 123, originally published 1990). Foucault also recognised this proliferation of law connected to the emergence of biopower (what he then still called “mechanisms of security”): “it is quite clear that this does not constitute any bracketing off or cancellation of juridico-legal structures or disciplinary mechanisms” (Foucault 2007, 7). Rather, “getting these systems of security to work involves a real inflation of the juridico-legal code” (Ibid.). What really changes for law “is the dominant characteristic, or more exactly, the system of correlation between juridico-legal mechanisms, disciplinary mechanisms, and mechanisms of security” (Ibid., 8).

3.2. *The changing role of law in governmentality: Towards the 'norm'*

Ewald thus argues that Foucault's notion of "the juridical" does not equate to all legislation (see also Golder and Fitzpatrick 2009, 35), and particularly addresses the different relation of biopower to law. Here the role of law is not yet fully understood:

"Foucault's analysis leaves open two questions: first, if the juridical is an inappropriate category to use in interpreting bio-power, how do we make sense of all those 'instruments of the law' (codes, constitutions, laws, regulations) that have developed and expanded during the era of bio-power? Second, if the actions of norms replaces the juridical system of law as the code and language of power, what role remains for law?" (Ewald 2010, 146; quoted also in N. Rose and Valverde 2010, 179)

Ewald's questions raise the problem of a practical interpretation of the law's turn towards the norm in the promotion of biopolitical priorities. As Foucault's statements above point out, the "dominant characteristic" or "correlation" of power exercises is undergoing change in governmentality. In this turn towards new priorities for governing, such as the life of populations, law becomes enmeshed with the operation of biopolitics and starts to be framed as a norm that translates biopolitical priorities. Elbe puts this change of direction, as part of a *governmentalisation* of power exercises, thus:

"For example, the much older institution of law (sovereign power) is increasingly used not just to augment the powers of the sovereign or the state but also to improve the welfare of populations by drafting new regulations – such as making it compulsory to wear seat belts, levying taxes on alcohol [...] The older forms of sovereign and disciplinary power [...] begin to play a much more subservient and "supporting" role for the wider purposes of managing the welfare of populations – giving rise to a complex 'triangle' of sovereignty, discipline, and governmental management." (Elbe 2009, 12)

This statement already refers to a much wider, and more contemporary, interpretation of the content of ‘law’, and highlights how the change towards the norm relegates more traditional forms of law to a supporting role. Instead of an emphasis on traditional fields of law, Rose and Valverde also argue that the emergence of the norm entails an overall

“[...] turn towards the minor, the mundane, the grey, meticulous and detailed work of regulatory apparatuses, of the control of streets, of the government of transport, of the law of health and hygiene [...], of the laws of property and trust, [...] of all the places where, in the bureaucratic working of our over-governed existence, laws, rules and standards shape our ways of going on, and all the little judges of conduct exercise their petty powers of adjudication and enforcement.”

(N. Rose and Valverde 2010, 546, originally published 1998)

This highlights the increasing relevance of previously “mundane” sectors of law in a process of governmentalisation of law containing a turn to biopolitical priorities – drawing attention to areas such as health and hygiene, but also the administration of property and trust. This chapter already set out the increasing relevance of technical knowledge and the control of such knowledge for biopolitical strategies. This finds its correlate in an increased importance of laws administrating technical sectors – which are now centrally involved in the realisation of governmental priorities.

However, Ewald states “the language of bio-power is purely technical and has almost nothing to do with the law as such” (Ewald 2010, 146), thus arguing that biopower’s mechanisms are not what Foucault considered ‘law’ in the first place. The distinction between technical types of law, norms, and “regulatory apparatuses” remains difficult, as not all fulfill the function of a norm in the same way. A law making seatbelts obligatory clearly introduces a new norm containing biopolitical priorities, but a system addressing the laws of property and trust does not establish norms as straightforwardly as that. In the case of IP, law introduces a method of normalising ‘accepted’ and ‘novel’ scientific knowledge and assigning clear ownership over this knowledge. IP is a technical area of law that is engaged in classifying technical knowledge – thus doubly relevant for the new art of governing. A predominantly US-American version of IPRs also became a global norm for IP by

virtue of the global reach of the TRIPS agreement, which sought to introduce a uniform minimum standard of IPRs worldwide. These aspects of IP's role as a norm have, however, first and foremost been analysed with reference to establishing property in an economic context – and not with reference to their relation to contestations over medical knowledge and the governing of life.

At the intensifying intersection between governing of life and also of the market, IP's function needs further attention, beyond declarations of law's changed status as a norm. The normalisation of knowledge and the normalisation of participatory regimes in research and the bioeconomy involve a complex negotiation of tensions. Relying on Golder and Fitzpatrick's instructive analysis of law within Foucault's work, the next section argues that at the intersection of life and the economy, law operates in an "illimitable" manner, "[engaging] responsively with exteriority, with an outside made up of resistances and transgressions" (Golder and Fitzpatrick 2009, 56 and 71). In this way, law as a tactics of government contributes to the resolution of tensions arising from, in the present case, the governing of life while ensuring the functioning of an economic system. Foucault's lectures specifically point out this constitutive function of law and thus turn the emphasis away from economic determinacy, highlighting the need to govern *for* the market for example by means of formal privileges.

3.3. Reversing the perspective: Governing through formal privileges

In his work, Foucault specifically proposed a different type of analysis to Marxist theory's overwhelming focus on the power effects of economic relations²³, or, the "‘economic functionality’ of power" (Foucault 1997, 14). With regards to law, Foucault intentionally reversed the analysis, arguing that "the juridical is clearly not part of the superstructure" (2008, 162), instead "the juridical gives form to the economic" in "an economic-juridical order" (Ibid., 163). The functioning market is no longer understood as a product of nature but as a deliberately constituted system that is being kept in its desired form by means of a juridical order. For example, the conditions for competition in the market are put in place by "formal privileges":

²³ Foucault was quite expressly non-Marxist: see for example Hunt & Wickham (1994, 33). Foucault questions: "Is power modeled on the commodity?" (Foucault 1997, 14), and argues for "different instruments, even if power relations are deeply involved in and with economic relations" (Ibid.).

“[t]he beneficial effects of competition are not due to a pre-existing nature, to a natural given that it brings with it. They are due to a *formal privilege*. [...] [C]ompetition as an essential economic logic will only appear and produce its effects under certain conditions which have to be carefully and artificially constructed” (Ibid., 120, emphasis added).

In similar way, IPRs are formal privileges conferring property rights necessary for creating value in a market economy. For a functioning market, the objects of property need to be stable and clearly identifiable – even more so in the case of scientific knowledge objects, which need to be artificially constructed in the form of exclusive monopolies in order to gain particular economic value. Without this, the dissemination of knowledge would remain “nonrivalrous”, as the sharing of knowledge does not diminish the value of the information itself (see for example Boyle 2008, 3).

Emphasising the constitutive role of law for the market, especially in the technical field of law comprising the rules of property and trust, consequently shows:

“that the relation between an economy of competition and a state can no longer be one of the reciprocal delimitation of different domains. [...] *Government must accompany the market economy from start to finish*. The market economy does not take something away from government. [...] One must govern *for* the market, rather than because of the market.” (Foucault 2008, 121, emphasis added)

This understanding reverses Marxist theory’s analysis of the relation between the forces of the market and of government, and instead stresses that the economy is a product of law. Connecting this point of reference for law with an understanding of law’s changes towards the norm shows that especially technical fields of law such as IP law are *governing* for the market – and in this function also increasingly contributing to the governing of the problematization of life. IP’s growing relevance thus confronts this field of law with tensions between two aims of governing, which need to be resolved incrementally by IP policy and jurisprudence.

Law’s constitutive relation to the economy emphasises the political relevance of the field of law, and highlights that it also constitutes an important site for

resistance: “we must be able to act on this ensemble and intervene in such a way as to invent a different capitalism” states Foucault, and stresses that instead of “economic interventionism”, interventions need to take the shape of “maximum legal interventionism” (Ibid., 167). This makes a clear case for renewed attention to economic law, understanding tensions within this sector as modes of resistance that can influence the constitution of the economy. Law therefore ceases to be an afterthought for political analysis, and rather becomes a central site of analysis.

The change towards a norm thus entails more than a change in status, it is rather a change towards becoming a site of contestation at which law is acting as a tactics governing challenges. Golder and Fitzpatrick show that law operates in two different modalities in governmentality, as a norm and also “in a constitutive engagement [...] [with] resistance and transgression”, in which it “extends itself illimitably in its attempt to encompass and respond to what lies outside its definite content” (Golder and Fitzpatrick 2009, 71). In this responsive mode, law can even “[disrupt] itself through becoming receptive of resistances that constantly challenge its position, its content, its being” (Ibid.). Using this understanding of law’s responsiveness to challenges sheds light on the role of law as a “tactics” determining “the right disposition of things” (Foucault 2000, 211).

At the intersection of governing for the market and governing for life, tensions are growing around the influence of genetic conceptions of life (the ‘genetic dispositif’) and the rising importance of IPRs for deriving economic value from life. Here, IPRs begin to respond to challenges regarding their relation to life while maintaining their economic function – thus becoming operative in the determination of the “right disposition of things”, as a tactics that accommodates challenges while maintaining order. Golder and Fitzpatrick’s understanding of law’s responsiveness towards challenges highlights that this accommodation of resistance can even lead to a disruption of law. The analysis of contestations surrounding IP’s relation to life in the coming chapters shows how engaging with different ‘truths’ of life could very quickly disrupt the economic function of IPRs, and how challenges relying on human rights and the notion of ‘market failure’ could contest IP’s legitimacy even on a fundamental economic level. However, it is also shown that as a tactics of government, IPs continue to play a variety of roles that maintain the function of the economy by limiting the participation of donors in the further use of their donated material, transferring ownership to other participants in the bioeconomy, and by

normalising scientific knowledge that ensures certainty and predictability instead of a complex genetic conception of life. As IPRs negotiate these pressures and roles, they change from a “mundane” form of technical knowledge to an important site of contestation in an unfolding governmentality.

Conclusion

The problem of governing life has intensified beyond Foucault’s original understanding, as an informational-genetic conception of life enhanced processes enabling the governing of individuals and populations – in the emergence of a genetic dispositif. At the same time, IPRs were found to be of growing importance for the neoliberal bioeconomy by generating speculative value from life in the life sciences. While the neoliberal economy turned towards banking on the life science sector’s future, IPRs became one of the key methods ensuring control over this form of future potentiality within the economy. IP thus became increasingly relevant for the economy and for the governing of individuals and populations. This gave rise to new strategies of challenge and intensified the continuing question of the definition of life for the purpose of governing and of economic utility.

This chapter set out a different analytic perspective on IP’s relation to life, which it argued can better account for tensions and developments that contradict an emphasis on commodification. The chapter introduced a framework for analysis of these developments in the coming chapters, which investigates the challenges of governing life on three different levels: contestations around normalised truth discourses, emerging new modes of subjectification, and new strategies for intervention in the name of life. This analytic of power illuminates how an increasing emphasis on the life and health of populations gives rise to changes in the role of law. The chapter argued that a growing relevance of knowledge over life turned IP into a central site of contestation within a “problematization” of life for governing. A deeper understanding of this process can account for growing debates around IP law, which in response acts as a tactics of government in accommodating challenges while also continuing to ensure IP’s function for the circulation of value in the economy.

Chapter IV Normalised truths - IPRs and the challenge of the genetic-informational vision of ‘life’

“Each age says everything it can according to the conditions laid down for its statements [...] [This is] perhaps Foucault’s greatest historical principle: Behind the curtain there is nothing to see, but it [is] all the more important each time to describe the curtain [...]” (Deleuze 2006, 46 f.)

“By [the late 60s] the genome had become widely perceived as an information system, an authorless Book of Life written in the speechless language of DNA.” (Kay 2000, 14)

The challenge of accommodating genetic conceptions of ‘life’ into the IP regime is particularly obvious in recent surprising changes concerning the patentability of information derived from human genetic materials. The US Supreme Court judgement in the *Myriad* case (*Assoc. for Molecular Pathology v. Myriad* (2013)) suddenly overturned IP’s long-established chemical-molecular understanding of DNA, and instead began to foreground DNA’s informational content. Paradoxically, this change marked a turn away from patentability of DNA in certain instances, and thus cannot be explained in terms of commodification alone. This chapter argues instead that this adjustment of ‘truth’ over life is evidence of IP’s confrontation with biopower exerted by the overwhelming influence of genetic-informational conceptions of life (or the ‘genetic dispositif’). This confrontation creates tensions between IP’s role of normalising predictable and stable forms of knowledge and the safeguarding of continued patentability of a genetic-informational conception of life. The fusion of genetic knowledge with the information sciences gave rise to forms of knowledge that can readily traverse the boundaries of science into areas of economic exchange and the governing of individuals and populations, but informational entities also challenge the accepted criteria for patentability.

As the patenting of sheer information is not strictly possible, the adoption of an informational-genetic conception of life by the *Myriad* decision came with a

caveat: complementary DNA (cDNA) continues to be seen as a man-made markedly different molecule that is not predominantly determined by its informational content. This uneasy compromise maintained the patentability of some forms of DNA – and thus fulfilled IP’s continuing role as a regime that is governing for the market. But this compromise also shows that IP law acted as a ‘tactics’ of government reconciling the growing influence of the genetic dispositif and the need for a continuing role of patents for the market. In this way, IP also contributes to the governing of genetic life as it continues to normalise predictable and stable versions of the informational-genetic conception of life. This elevates some forms of scientific knowledge over others, which emphasise complex environmental interactions, such as systems biology and epigenetics. IP thus continues to maintain a central truth as a point of reference for the governing of life and its economic use.

1. Intellectual Property Rights and the Molecular Vision of Life: Patenting the Contested Truth of ‘Life’

The relation of IPRs to ‘life’ has been a contested one – especially where it came to the patenting of human genetic sequences. Science’s ethical treatment of research subjects and the relation to patients and donors of tissues has been problematic throughout history²⁴, and the patenting of human genetic materials has been one of the latest instances in this conflict. However, questions about the ethical treatment of life fail to interrogate IP’s relation to particular scientific ‘truths’ about life. IP law is central to the intersection of knowledge and the economy, and exercises significant power on the direction of research endeavours by endorsing a normalised canon of scientific advances, and supporting a predominant scientific paradigm. But this process of the normalisation of knowledge contains challenges and compromises, as for example in the recent change of IP’s understanding of life from a chemical-molecular notion of DNA to an informational-genetic one. This conflicted and ambivalent development cannot be adequately explained by a commodification critique alone, as it diminished the extent of the ‘commodification’ of life instead of further intensifying it. This change can be better explained, it is argued, with reference to the overwhelming success of the informational-genetic conception of life

²⁴ See for example the already mentioned notorious story of Henrietta Lacks and the HeLa cell line (Hudson and Collins 2013; Collins 2013; Skloot 2011; Skloot 2013).

(‘the genetic dispositif’) over the course of the 20th century, influencing research agendas and the identities of individuals far beyond the field of the life sciences.

IP’s changing conception of life is set out first in its fundamental opposition between DNA as “occurring in nature” and DNA as a man-made “composition of matter” in the cases of *Diamond v Chakrabarty* (1980) and *Howard Florey /H2 Relaxin* (1995). This distinction is complicated by the *Myriad* cases (*Assoc. for Molecular Pathology v. Myriad* [2013]), which discussed whether DNA is either essentially “informational” or merely a “markedly different” chemical molecule. This discussion shows a strikingly delayed impact of the truth discourse of the *informational* character of genetics, which was held off by “the life/nature-is-nothing-more-than-chemistry argument” (Carolan 2010, 117; Calvert and Joly 2011) for a long time. The *Myriad* decision maintained a tenuous division between elements “occurring in nature” and those deemed “man-made” – but also adopted an informational understanding of DNA. IP’s unprecedented preoccupation with “the ontological problem of our humanness” (Cooper 2008, 146) thus produces challenges that can be better interpreted as part of ongoing processes of accommodation between the two main governmental aims of life and the market.

1.1. Patenting DNA: ‘Occurring in Nature’ or man-made ‘Composition of Matter’?

The patenting of genetic material became routine practice in the 1990s, when the human genome was in the process of being deciphered. Great expectations were being held when it came to this new vision of ‘life’, anticipating the revelation of the ‘blueprint’ of all living beings on the molecular level. The driving force behind the increased patenting of human genetic material was the hope of finding ‘special’ strains of genetic sequences (to put it briefly) that showed resistances to certain diseases, or that were connected to the development of diseases in some way - which led to a relative ‘hype’ in this area.²⁵ In the patenting of such material, the definition of the essential nature (or ‘truth’) of genetic material became the central question for the determination of whether it could constitute patentable subject matter.

²⁵ A prime example is the story of *deCode*, the company founded by Craig Venter, which aimed to identify and isolate specific ‘special’ strands of DNA with the help of the Icelandic biobank and full access to Icelandic health records. For a while the company offered ‘disease risk tests’ over their website www.decode.com (accessed 17.1.2012), but the expected breakthrough in monetary and medical terms did not materialise (Pálsson and Rabinow 1999; H. Rose 2003; Fortun 2008). The company merged with Amgen in the end of 2012, and has since abstained from providing personal genome scans as part of this merger.

1.1.1. *Diamond v Chakrabarty* (1980) – “a new bacterium with markedly different characteristics”

The US²⁶ practice of granting patents on genetic material goes back to the decision of *Diamond v. Chakrabarty* (1980) 447 U.S. 303, which decided for the first time that “a live, human-made micro-organism is patentable subject matter” – confirming the Court of Customs and Patent Appeals’ determination “that the fact that micro-organisms are alive is without legal significance for purposes of the patent law” (*Diamond v. Chakrabarty*, Preamble). This case was concerned with the patenting of a “genetically engineered bacterium capable of breaking down crude oil, a property which is possessed by no naturally occurring bacteria” (Ibid.).²⁷ Starting with this patenting of a “man-made” micro-organism, a determination of the essential characteristics of ‘life’ became part of IP’s purview. In the wake of *Diamond v. Chakrabarty*, the US Patent Office laid down this new approach in an official notice stating that it is “now examining claims directed to multicellular living organisms, including animals” (1077 Official Gazette 24, 21st April 1987; quoted after Jaenichen, McDonell, and Haley Jr. 2002, 8). At this point, this practice was still limited to non-human organisms, but these cases established the foundation of IPR’s relation to ‘life’, which became internationally influential with the formation of the US’ industry-influenced TRIPS agreement (1994) and its reach to the rest of the world (Sell 2003).

The patenting of ‘life’ needs to resolve the fundamental question of how genetic materials should be understood for the purposes of determining ‘novelty’ and the ‘inventive step’ rewarded by the patent. A standard definition of a patent is that it “is a monopoly which [...] lasts for a maximum of 20 years. To be patentable, an invention must be new, show an inventive step, be industrially applicable and not fall into one of the excluded categories of invention” (Colston and Galloway 2010, 4).

²⁶ The US approach has a fundamental effect on IP law in the rest of the world. The US remain the determining force in the sector and exported their view of the matter to the rest of the world via the means of international treaties such as TRIPS and international organisations such as WIPO. The most important cases in this field are those determined by US courts, and, to a lesser degree, those determined in the EU by the European Patent office and also the (separate) EU Courts. Most of the biotech sector reliant on IPRs is still located in the US and the EU, despite the increasing prominence for example of India.

²⁷ Further cases involving ‘man-made’ varieties included the patenting of seed and tissue cultures of maize in *Ex parte Hibberd*, 227 U.S.P.Q.443 (Bd. Pat. App. & Int. 1985), and of oysters in *Ex parte Allen*, 2 U.S.P.Q.2d 1425 (Bd. Pat. App. & Int. 1987), thus extending the principle to “multicellular animal varieties” (Jaenichen, McDonell, and Haley Jr. 2002, 8).

What is most notable for the present context is that patents are granted for *inventions*, not *discoveries* (such as chemical elements or natural laws), a distinction that is contained in the idea of an *inventive step*, in which the scientist invests his or her own creativity and comes up with something new that, as a product of their efforts, warrants protection. This distinction between inventions and discoveries is central to IP law, and especially central to the issue of patentability of human genetic materials.

In line with the question of the inventive step, the question of patentable subject matter was viewed in *Diamond v. Chakrabarty* as one of whether the material occurred “in nature” or represented a man-made “composition of matter”. The court considered the exclusion of discoveries, stating that

“a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are “manifestations of . . . nature, free to all men and reserved exclusively to none.” *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 130” (*Diamond v Chakrabarty* p. 309).

The court argued that in this case, the micro-organism in question was not ordinarily found in nature, hence: “Judged in this light, respondent's micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter -- a product of human ingenuity “having a distinctive name, character [and] use.” *Hartranft v. Wiegmann*, 121 U. S. 609, 121 U. S. 615 (1887)” (*Diamond v Chakrabarty* p. 309).

Interestingly, the Court elaborated on the distinction in more detail than strictly necessary for the inventive step, stating “the patentee has produced a new bacterium with markedly different characteristics from any found in nature, and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101” (*Diamond v Chakrabarty* p. 310). This passage introduces the concept of “markedly different characteristics”, which became central in later cases determining the patentability of genetic material – and the question of whether they can all be regarded as “man-made”.

The difference between the Chakrabarty micro-organism and other patents on ‘life’ becomes apparent when compared to a later case in the European courts, *Howard Florey /H2 Relaxin* [1995] EPOR 541, where the patent claimed “a genetically engineered human protein, H2 relaxin, which women produce during childbirth to soften the pelvis” (MacQueen et al. 2011, 442). This application concerns a protein found in nature, however, the argument made here is that it is materially changed in the procedure of isolation from the human donor – a process that takes place in the isolation of any genetic material from the donor’s body for the purposes of research. This change does not amount to the “manufacture” of a new micro-organism as in the *Chakrabarty* case – but it is still perceived as an inventive step creating something markedly different.

1.1.2. Howard Florey /H2 Relaxin (1995) – “DNA is not ‘life’, but a chemical substance”

The essential characteristics of this marked difference are however contested, as the deliberations about DNA as either a chemical substance or as an informational representation of ‘life’ show. A few years after *Diamond v Chakrabarty*, the *Howard Florey/H2 Relaxin* case directly addressed the question of the patentability of human genetic material (judged by the European Patent Office’s (EPO) Opposition Division, thus not affecting rules in the US)²⁸. The European Parliament’s Green Party complained, amongst other, that the isolated DNA “invention” contained nothing novel; that it constituted a discovery; that the “use of a particular female condition (pregnancy) for a technical process oriented towards profit” [...] “constitutes an offence against human dignity”; that the practice described in the patent “amounts to a form of modern slavery since it involves the dismemberment of women and their piecemeal sale to commercial enterprises throughout the world”; and that “human life is being patented”, which is “intrinsically immoral” (*Howard Florey / H2 Relaxin*, p. 549, at 6.1). They relied on Art. 53(a) EPC, which declares patents inadmissible that are “contrary to ‘*ordre public*’ or morality”.

²⁸ There are significant differences between the US and the European approach to patentable subject matter. Europe focuses on the “‘inventive step’, [...] the US interpretation focuses on ‘non-obviousness’ [...] This latter is a lower threshold and consequently means that genetically engineered products remains [*sic.*], potentially at least, more easily patentable in the US than in Europe” (MacQueen et al. 2011, 517).

The Opposition Division of the EPO rejected all of these claims and pointed out, amongst other, that “every evidence indicates that this practice is perfectly acceptable to and even welcomed by the vast majority of the public” (p. 550, at 6.3.1). Furthermore, patents on genes

“do not confer on their proprietors any rights whatever to individual human beings [...] No woman is affected in any way by the present patent – she is free to live her life as she wishes and has exactly the same right to self-determination as she had before the patent was granted. [...] The only stage at which a woman was involved was at the beginning of the making of the invention, as a (voluntary) source for the relaxin mRNA.” (*Howard Florey / H2 Relaxin*, p. 550-551, at 6.3.3)

The Court thus confirmed that an isolated protein was markedly different to that found in nature.²⁹ Elaborating on the essence of this difference, the EPO’s Opposition Division insisted most crucially on the determination “that DNA is not ‘life’, but a chemical substance which carries genetic information and can be used as an intermediate in the production of proteins which may be medically useful” (p. 550, at 6.3.4). DNA was thus understood as predominantly a chemical substance which has the coincidental attribute of carrying genetic information – making ‘life’ not the essence, but a mere feature of this chemical.

This understanding of a “marked difference” between a genetic sequence isolated from the body and a sequence still within the human body is also echoed by the EU’s 1998 *Biotech Directive* (*EU Directive 98/44/EC*), which engages with the definition of ‘life’ and the treatment of genetic materials in more detail than US documents.³⁰ While Art. 5 (1) of the Directive states that the “simple discovery” of one of the elements of the human body “at the various stages of its formation and

²⁹ The isolation process has become so commonplace that its results are by now no longer considered “non-obvious”. *Ex parte Kubin* (83 USPQ2d 1410 Bd. Pat. App. & Int. 2007) found an “increased level of skill in the art” overall (Yamanaka 2008, 1086). The notion of ‘gene patents’ has not been challenged by *Ex parte Kubin* – “rather it corrects the anomalously low threshold for nonobviousness established by *Deuel*” (Cook-Deegan and Rai 2009, 122). *In re Deuel* (1995 34 USPQ 2d 1210 [Fed. Cir. 1995]) established “*per se* non-obiousness for all new DNAs obtained from their amino acid sequences” (Ducor 1996, 35, emphasis in original).

³⁰ The European approach to patenting of ‘life’ has historically been more restrictive than US practice (see previous footnote 28).

development [...] including the sequence or partial sequence of a gene, cannot constitute patentable invention”, Art. 5 (2) then states “An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.” This is as long as “the rights conferred by the patent do not extend to the human body and its elements *in their natural environment*” (Recital No. 20 Preamble, emphasis added). While “a mere DNA sequence without indication of a function” is not patentable according to Recital No. 23 Preamble, this means that ‘isolated’ sequences are generally patentable – just like in the US. The *European Patent Convention (EPC)* also shares this understanding of ‘man-made’ sequences.³¹

1.2. The Myriad Case: DNA as ‘information’ or a ‘markedly different’ chemical molecule?

However, the understanding of genes as chemical molecules (also referred to as the “life/nature-is-nothing-more-than-chemistry argument” by Carolan 2010, 117) has been drawn into question by the latest instance of the debate conducted in the US in the *Myriad case*. This case started at the District Court level and rose to the level of the US Supreme Court in 2013, where the nothing-more-than-chemistry paradigm was finally partially overturned. The different judgements issued over the course of this case are an excellent showcase of IP law’s deliberation of different competing ‘truths’ over genetic materials within the field of IPRs.

The detailed reflections at the District Court, Court of Appeals, and Supreme Court level concerning the ‘nature’ of DNA and the isolated versions of sequences reveal a conflict of different perspectives on ‘life’ in this landmark case, which resulted in a surprising turn away from the previously established chemical-molecular paradigm. Instead the Supreme Court finally endorsed a genetic-informational understanding of life, but also partially upheld the notion of isolated sequences’ “marked difference”. This shows how the Court in the last instance seeks to reconcile

³¹ This convention contains the European Patent’s Office (EPO) guidelines for the issuing of patents. The equivalent of the EPO and the EPC in the US is the US Patent and Trademark Office (USPTO) with the US Patent Act (1952), now under United States Code Title 35, setting out patent eligibility in section 101. In the UK the Intellectual Property Office (IPO), the Patents Act (1977, as amended) and the Patents Rules (2007) consolidate relevant legislation and provisions. Section 1 of the Patent Act set out the patentability of inventions, requiring novelty, an inventive step, and industrial application. See also Bently & Sherman (2009, 346 f.).

the turn to the informational view of ‘life’ with the notion of patenting of human genetic sequences in general – thus extending an olive branch to the biotech industry reliant on those patents. This seemingly contradictory judgement can be better understood as part of an ongoing process of accommodation in a new art of governing, showing how the central influence of genetic- informational accounts of life is being balanced against the need of the market for IPRs.

1.2.1. *The District Court and the Court of Appeals*

The landmark *Myriad* case concerned Myriad Genetic Ltd.’s patents on the BRCA 1 and 2 cell line, which are “two genes linked to susceptibility for breast and ovarian cancer (...). The risk of falling ill increases if these genes show certain mutations” (WIPO 2006).³² Myriad registered patents on the isolated cell lines, on methods of analysing and comparing this information with other cell lines, and methods to screen for those mutations (for example with the help of test kits).³³ This patent was initially challenged in 2010 in the US District Court for the Southern District of New York, where Judge Sweet declared the practice of patenting of genetic information to be *in general* invalid in *Association for Molecular Pathology et al. v. US Patent and Trademark Office et al.* (also called *ACLU v Myriad Genetics*, 2010, US District Court for the Southern District of New York, 09 Civ. 4515).

In this surprise verdict at the district level, Judge Sweet found that “[b]ecause the claimed isolated DNA is not markedly different from native DNA as it exists in nature, it constitutes unpatentable subject matter under 35 U.S.C. §101”³⁴ (*ACLU v Myriad Genetics* at p. 135). In this, he states, the judgement follows “the clear line of Supreme Court precedent (...) establish[ing] that purification of a product of nature, without more, cannot transform it into patentable subject matter”, pointing out that “the purified product must possess ‘markedly different characteristics’ in order to

³² The test for these mutations has for example motivated Angelina Jolie to have a double mastectomy in 2013 and further preventative yet very invasive treatment (Jolie 2013; 2015). This high profile example shows what kind of choices the ‘pre-symptomatic ill’ (Wehling 2011, 234) are facing on the basis of genetic ‘truth’. This emerging “somatic ethics” (N. Rose 2008a) will be discussed in more detail in the next chapter. This notion of responsible conduct also highlights why these tests are in particular demand.

³³ These tests, of which Myriad is the sole provider after having enforced these patents against its competitors, cost up to 3000 dollars a piece (Pollack 2007). This very high price is the reason why the patent on BRCA 1 was only upheld within the EU in a limited form. The patent on BRCA 1 had been revoked there after an apparent unwillingness to offer licenses “at a reasonable price” had “angered the genetic community” according to Gert Matthijs from the Center for Human Genetics, University of Leuven, Belgium (quoted from Siva 2009, 8).

³⁴ For full text of 35 U.S.C. §101 see footnote above.

satisfy the requirements of §101” (*ACLU v Myriad Genetics* at p. 121). Crucially, he states “Myriad’s focus on the chemical nature of DNA (...) fails to acknowledge the unique characteristics of DNA that differentiate it from other chemical compounds” (at p. 122). Thus the usual analogy to chemical compounds without regard to the specific content of DNA is set aside, and DNA is for the first time seen as “a physical embodiment of information” (p. 125), whose “informational quality is unique among the chemical compounds found in our bodies” (p. 123). This leads to the finding that since the informational content is not changed in the process of isolation, the isolated genetic sequence is not “markedly different” to the sequence occurring in nature – and thus cannot be patented.

This determination could have taken away the basis for *all* basic human gene patents registered in the US.³⁵ However, in July 2011 the US Court of Appeals for the Federal Circuit overturned the judgement in part, except where it came to method claims.³⁶ With regards to the nature of the patentable material, this Court returned to the notion that “the challenged claims are drawn to patentable subject matter because the claims cover molecules that are markedly different (...) from molecules that exist in nature” (*Association for Molecular Pathology et al. v. US Patent and Trademark Office et al.*, 2010-1406, at p. 41). “Isolated DNA is not purified DNA”, rather, “it has (...) been manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body” (at p. 42). This re-instated the previous *status quo* and the focus on the chemical nature of the molecule, not the informational content.

1.2.2. *Myriad at the Supreme Court*

But in yet another surprising³⁷ development, this judgement was partially overturned again by the US Supreme Court in 2013 in *Association for Molecular Pathology, et*

³⁵ For an impression of the discussion at the time see for example Morgan & Haile (2010), Hoffenberg (2010).

³⁶ The court followed the district court’s judgement and declared “Myriad’s method claims directed to “comparing” or “analyzing” DNA sequences” as ineligible patent matter, as they “cover only (...) abstract, mental steps” (at p. 8). But Myriad claims that it still retains “237 method claims for BRCA*Analysis* which were not affected by this ruling and remain in full force and effect” (Myriad Genetics Inc. 2011; 2013).

³⁷ Or maybe not so surprising after all – the US government supplied an *amicus curiae* brief to the proceedings in 2012, in which it was argued that “[s]ynthesized genetic materials such as cDNA molecules are patent-eligible subject matter, while isolated but otherwise unmodified genomic DNA is not” (US Department of Justice 2012; Pollack 2010).

al., Petitioners v. Myriad Genetics, Inc., et al. 569 U.S. 12-398 (2013). This court of the highest instance determined that

“a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring” (*Assoc. for Molecular Pathology v. Myriad* (2013) p. 1).

This distinction draws a very fine line between the isolated DNA sequence that was claimed in some of Myriad’s patents, and the sequence in complementary DNA (cDNA), which has to be synthetically created in the laboratory, and which was claimed in some of the other patents of Myriad. As this judgement sets out in detail, the Court of Appeals had in its judgement been divided on the rationale for patentability of isolated genetic sequences, but had all agreed on the patentability of cDNA (*Assoc. for Molecular Pathology v. Myriad* (2013) p. 10). Judge Sweet of the District Court however had not seen this as a “marked difference” (*Assoc. for Molecular Pathology v. Myriad* (2013) p. 7).

Regarding isolated sequences, the Supreme Court decided, with reference to the requirement of “markedly different characteristics from any found in nature” set out in the *Chakrabarty* case, that “[i]n this case, by contrast, Myriad did not create anything”, and that “[t]o be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention” (at p. 12). Most importantly, the Court brushed aside the previous understanding of genetic sequences as primarily chemical molecules. It argues

“[n]or are Myriad’s claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule. Myriad’s claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes.” (*Assoc. for Molecular Pathology v. Myriad* at p. 14)

This constitutes a dramatic turn away from previous practice, and marks the moment in which IP begins defining ‘life’ in informational terms. *Information* as the determining feature of the genetic *code* is now accepted as the central characteristic of the genetic sequence – containing a noticeably “scriptural element” (Kay 2000), as a DNA sequence is rendered in the format of a “sequence of the individual subunits (bases) of the nucleic acid that determines hereditary features” (Lewin 2004, 1) - these can be expressed in a written form, which is a pre-requisite for any potential application for IPRs.

However, the judgement’s change towards the informational paradigm does not completely overturn the notion of markedly different man-made versions of DNA. The Court determined that cDNA “does not present the same obstacles to patentability as naturally occurring, isolated DNA segments” (at p. 16). It rather is an “exons-only molecule that is not naturally occurring” (Ibid.). Here, interestingly, the structure of the molecule is deemed to be the most significant aspect once again – and the sheer informational structure of the cDNA strand is not considered. This is contrary to the fact that “[t]he nucleotide sequence of cDNA is dictated by nature, not by the lab technician” (at p. 17) – as submissions argue “[t]hat may be so, but the lab technician unquestionably creates something new when cDNA is made” (Ibid.). The character of this ‘new something’ is not set out in detail, and it is acknowledged that due to the informational sequence being the same, “a short strand of cDNA may be indistinguishable from natural DNA” (Ibid.). The fact that the Supreme Court is maintaining this distinction shows that it is unwilling to follow the District Court’s complete turn towards the informational definition. Rather, the notion of a “marked difference” created by an inventive step is still upheld – and thus the patenting of some form of genetic information.

2. Law as one of the ‘multiform tactics of government’: Maintaining IP while accommodating informational-genetic conceptions of life

Rather than enabling further instances of commodification, the Myriad decision’s changed view of the ‘truth’ about life is attempting to reconcile the informational understanding of the genetic code with a continued existence of IPRs on information derived from human genetic materials. The result is a compromise predicated on an

enduring finding of “marked difference” between cDNA and isolated DNA. This rendered some of Myriad Genetics’ patent claims void, however, it also held up others. This chapter argues that this accommodation shows that the Court is navigating the overwhelming scientific and social influence of an informational-genetic conception of life (the ‘genetic dispositif’) while at the same time seeking to maintain IPRs as a tool for the bioeconomy, and for the normalisation of knowledge. In responding to the challenge of the move of knowledge over life onto the genetic level, law as a “tactics” of government is re-adjusting the “right disposition of things” (Foucault 2000, 208). At stake in this adjustment is nothing less than the continued existence of the IP regime in the area of genetic materials, and its important functions regarding the maintenance of a central canon of knowledge (see this chapter), and as an area of expert knowledge enabling the conduct of “governing at a distance” (Miller and Rose 2008, see next chapter). Knowledge is crucial for governing according to the right disposition of things, and the change towards the informational-genetic conception of life intensified the utility of knowledge of “the nature of things” (Foucault 2008, 28) by seamlessly integrating knowledge of the individual with that of the population, and also – through the medium of information - with further use in the bioeconomy.

2.1. Governing the normalisation of technical knowledge

Foucault’s account of the emergence of the new art of governing emphasized the central role of scientific method and medical knowledge, in particular with regards to strategies aimed at the fostering of life and health of the population. These “include forecasts, statistical estimates, and overall measures” and involve “a set of processes such as the ratio of births to deaths, the rate of reproduction, the fertility of a population, and so on” (Foucault 1997, 243 and 246). These sources of information then gave rise to potential biopolitical strategies. Initially this knowledge was gathered from observations of individuals, compiled in an “apparatus of writing” and analysed according to a new comparative system “that made possible the measurement of overall phenomena, [...] the calculation of the gaps between individuals, their distribution in a given ‘population’” (Foucault 1977, 190). The notion of a “population” for the purposes of governing could only emerge as a result of this collection of individual cases.

Knowledge is thus one of the central factors that ensure the appropriate operation of government. Foucault points out “[t]he constitution of knowledge [*savoir*] of government is absolutely inseparable from that of a knowledge of all the processes related to population in its larger sense – that is, what we now call the economy” (Foucault 2000, 217). This points to a contingency of ‘truth’ upon measurements of processes in the population – identifying “the nature of things”, and upon an economic way of governing – determined by “the question of the too much and the too little” of governmental intervention (Foucault 2008, 28). However, Foucault asks “[h]ow can the phenomena of ‘population’, with its specific effects and problems, be taken into account in a system concerned about respect for legal subjects and individual free enterprise?” (Ibid., 317, quoted also in Dean 2010). A fault line of potential conflict thus runs between the notion of “political economy” and governing for “the optimization of the life of the population” according to the nature of things (Dean 2010, 120). This underlying tension between priorities of governing is governed by laws in the mode of a responsive “tactics” of governing (Foucault 2000, 211), navigating demands made on the basis of technical knowledge while also still ensuring the economy (i.e. appropriateness in economic terms) of this disposition of things.

This perspective sheds new light on the uneasy compromise in the *Myriad* decision, reinterpreting it as the product of a confluence of two different dynamics prioritising on the one hand the continued existence of IPRs on knowledge derived from human genetic materials, and on the other hand seeking to contribute to the normalization of the genetic-informational conception of life. In managing this tension, IP law is becoming governmentalised. Previously, “the life/nature-is-nothing-more-than-chemistry argument” (Carolan 2010, 117) effectively “closed down” debates about the patenting of genetic sequences, and settled definitional arguments as predominantly “technical” issues (Calvert and Joly 2011, 13 f.). In this, patent law provided specific rules that enabled the patenting of genetic sequences, and turned these otherwise “fuzzy and uncertain objects” into tradeable entities (Ibid., 16). Genes are fundamentally “uncertain” and hybrid objects, as they “[consist] not in a structure but in the process that ‘expresses’ or actualises a given molecular strand” (Pottage 1998, 747). As long as IP law provided clear patentability criteria for these objects, it succeeded in normalising an understanding of DNA that ‘governed’ for the market. However, the *Myriad* judgement’s turn complicated this function considerably, and

showed that the adoption of the informational-genetic paradigm causes tensions that could seriously overstretch IP law's parameters.

The *Myriad* decision reflects the emergence of a new scientific paradigm. Changing paradigms of (scientific) knowledge are closely connected to changes in paradigms of governance (Foucault 1970). Within a paradigm³⁸ of knowledge, an apparatus or a *dispositif* of knowledge connects the various sites of decision-making at the macro and micro level of governing, containing a particular constellation or congruency of understandings of “labour, life, language” (Ibid., 250 ff.) – a shared basic epistemology³⁹ making the development of sciences like biology, economics, and linguistics possible. These elements contain an epistemology that shaped for example the modern system – and within this system, knowledge derived in accordance with this epistemology needs to be seen as a central concern of power relations, or “power-knowledge”. Information science has emerged as the predominant paradigm of the twenty-first century and given rise to a *dispositif* that connects the life sciences with computer science and the economy.

Within this paradigm, technical scientific knowledge needs to be understood as “power-knowledge”, which is the result of a deeply politicized process of contestations between different forms of knowledge.⁴⁰ A normalised canon of scientific knowledge is a result of a struggle between different forms of knowledge, and is constantly threatened by “insurrections” of other formerly “disqualified” or marginalised knowledges (Foucault 1997, 9). Here, a battle “not [...] between knowledge and ignorance, but an immense and multiple battle between knowledges in the plural [took place] – knowledges that are in conflict because of their very morphology, because they are in the possession of enemies, and because they have *intrinsic power-effects*” (Ibid., 179, emphasis added). These power effects, especially on the level of control and ownership of knowledge, are founded “in a society where knowing the secret behind technological knowledge was a source of wealth” (Ibid.). IPRs are thus immersed in a political sphere at the intersection of economic governing and the determination of the nature of things, at the centre of “an immense struggle over the economic inductions and power-effects that were bound up with *the*

³⁸ For the notion of the paradigm see Agamben (2009b). This overarching notion of a paradigm of knowledge is not to be confused with *science*, as Deleuze points out (2006, 44).

³⁹ Deleuze highlights the centrality of this episteme: “Present or past, the visible is like the articulable: they are the object not of a phenomenology, but of an epistemology” (2006, 44).

⁴⁰ On the general political dimension of the natural sciences see for example amongst others Latour (1987), Jasanoff (2004; 2005).

exclusive ownership of a knowledge, its dispersal and its secret” (Ibid., 180, emphasis added).

IP fulfils different functions within these struggles between competing knowledges. It establishes control over knowledge and research agendas, and enshrines a particular ‘normalised’ version of scientific truth in an officially recognised instrument such as a patent – assigning and amplifying science’s “intrinsic power-effects”. The *Myriad* decision’s turn towards an informational-genetic conception of DNA can be interpreted as a continued fulfilment of these important functions of the IP regime, which go beyond the sheer commodification of DNA sequences. Instead of prioritising patentability, the decision inscribed or normalised the informational-genetic paradigm in IP law, thus conferring power-effects on this type of knowledge. It contributes to the governing of ‘life’ by further normalising the genetic dispositif. As already pointed out in the previous chapter, genetic knowledge seamlessly integrates knowledge over the individual and the population within *one* code. The knowledge and ownership of this code is thus a particularly significant power-effect, crucial for questions of research projects, grants, publications, assessments of profitability, and also for personal insurance, questions of identities, and personal life choices. In the process of this normalisation, IP law also marginalises other competing understandings of life and the role of DNA, such as epigenetics and systems biology (see below). In this way, IP promotes research agendas that generate a type of ‘predictable’ knowledge over life.

2.2. Governing science: The central dogma and the making of the ‘genetic dispositif’

The life science’s turn towards an informational-genetic understanding of life was not purely coincidental, as Kay points out. Kay’s study on the emergence of the DNA code as the paradigm for scientific research shows in detail how a change of ‘truth’ over life came about as a series of political decisions. After the Second World War, a research programme focussing on a “molecular vision of life” (i.e. the establishment of the discipline of molecular biology) was heavily promoted by institutions such as the Rockefeller Foundation and the California Institute of Technology (Kay 1993; see also H. Rose and Rose 2012; Yoxen 1981, 91). This molecular vision of life then

morphed into the genomic vision of life, as the informational paradigm⁴¹ colonised the biological and biochemical sciences. Importantly, the Rockefeller Foundation's "Science of Man"⁴² agenda (Weaver 1933) went beyond the immediate scientific context from the beginning and confidently aimed at becoming a comprehensive new vision of life in the sense of a *dispositif*.

"The motivation behind the enormous investment in the new agenda was to develop the human sciences as a comprehensive explanatory and applied framework of social control grounded in the natural, medical, and social sciences. Conceived during the late 1920s, the new agenda was articulated in terms of the contemporary technocratic discourse of human engineering, aiming toward an endpoint of restructuring human relations in congruence with the social framework of industrial capitalism. [...] Within that agenda, the new biology (originally named "psychobiology") was erected on the bedrock of the physical sciences in order to rigorously explain and eventually control the fundamental mechanisms governing human behavior, placing a particularly strong emphasis on heredity." (Kay 1993, 8)

This shows the breadth of this agenda, which had far-reaching effects beyond the scientific sector.⁴³ Kay sets out the historical background of the molecular biology programme supported by financial backing first from the Rockefeller Foundation, then the US military, and finally from the National Institute of Health (NIH) (Ibid., 8 and 9). Francis Crick's "central dogma" of the unidirectional mechanism of "DNA makes RNA makes protein makes us" dominated this scientific programme for most of the twentieth century (Crick 1970; the term "dogma" proved controversial but illustrates the ambition of this specific interpretation of DNA, see Crick 1990, 109; H. Rose and Rose 2012, 31). However, while it still enjoys virtually unchallenged

⁴¹ The molecularization of 'life' entailed also an *informationalisation* of the content of life, in which the basic content of 'information' is conceived of in a "thoroughly quantitative and statistical" way (Thacker 2005a, 97; 2005b; 2009; see also Dillon and Reid 2009, chapter 4).

⁴² See for example Warren Weaver's founding document *Science of Man*, which states for example the "conviction that discoverable laws govern the basic physiological and mental activities of man", meaning that a wide range of human behaviour no longer was "outside the range of rational analysis" (Weaver 1933).

⁴³ Kay argues for the understanding of "the human sciences as a comprehensive explanatory and applied framework of social control grounded in the natural, medical, and social sciences" (1993, 8).

acceptance in the cultural sphere, its predominance is increasingly coming under attack in the scientific sector, as the end of this chapter will set out.

Advances in the information sciences⁴⁴ were central to the development of the informational-genetic conception of life (and the ‘genetic dispositif’). The abstract, “disembodied” conception of information made the definition of the qualitative content of life effectively lose its connection to the physical world and became “one of the major assumptions behind the gradual “encoding” of genetics during the same period” (Thacker 2005a, 98). Kay highlights the scriptural element of this code (reminiscent of the apparatus of writing establishing the corpus of statistical knowledge of populations of the 19th century) and states “this view of the genome as information system, a linguistic text written in DNA code, has been guiding theories and practices of molecular biologists since the 1950s” (Kay 2000, xv; also Nelkin and Lindee 1995). In this “[genetic] reductionist framework what is of greatest value is the code”, Thacker argues, and “this relationship between DNA, database, and value is made more concrete in commercial genome databases [...] as well as in the U.S. PTO database categories containing patents on genes and gene-related compounds” (Thacker 2005a, 101 f.). IP law thus concretises the informational content of life, and acts as a depository of the disembodied genetic code.

This ‘informationalised’ abstract scriptural notion of life traversed the boundaries of biology and economy, giving rise to ‘value’ that can be circulated in the bioeconomy. IPRs are crucial for both defining the monopolistic knowledge-object that can be circulated, and also for the accrument of value on the basis of licensing fees and monopolies in the market. But IP law also became immersed in a wider political project outside of science and the economy. The “Science of Man” vision of life became a very successful determining force in identity formation, a formidable point of reference for definition of a new somatic ethics (N. Rose 2008a)⁴⁵ determining the parameters of ‘responsible’ healthy living of individuals and populations, and the gene became a “cultural icon” (Nelkin and Lindee 1995) in its own right. A genetic dispositif emerged that contained an all-encompassing genetic

⁴⁴ For an interesting and comprehensive account of the advances in the information sciences and the connection to the life sciences, see Dillon & Reid (2009), Chapter 4, ‘Informationalizing Life’.

⁴⁵ For the rights and responsibilities arising in this new somatic ethics, see next chapter. An example would be new responsibilities for healthy living according to ones’ genetic risk profile established by a personal genomic scan. Another responsibility, which will be explored in the next chapter, is the increasing pressure to contribute to research by donating materials and information – as a ‘responsible’ patient.

reductionist account of the essence of life in the scientific sector and in the cultural realm, promoted by its abstract informational promiscuity.

Cooper argues that the connection between the emergence of the informationalised life science sector and neoliberal economy was especially productive, leading to a huge influx of venture capital (Cooper 2008) and increasing the dominance of the genetic-molecular vision of life. This connection has also been noted by other scholars (for example N. Rose 2007b; Dillon and Lobo-Guerrero 2008; 2009). The connection between informational-genetic accounts of life and the circulation of this information in the economy has been one of the distinguishing features in the “neoliberal revolution” as Cooper points out (Cooper 2008, 3). She understands neoliberalism as a qualitatively different stage of governmental and economic development to that of liberalism, in which an intensified emphasis on financialisation and an enhancement of societal differences are the result of the limitation of the state’s role to the construction and maintenance of the financial markets and the conditions for trade within it.

She describes this process as an “ever-tighter alliance between state-funded research, the market in new technologies, and financial capital” (Ibid.), and argues

“the very value of knowledge [...] is the result of a quite deliberate self-transformation of the U.S. economy and that of its allies, one that was pursued through the international organizations created in the post-World War II era, but with the ultimate effect of entirely redefining the landscape of world trade and imperialism.” (Ibid., 57)

The effect of this strategy was very noticeable: “[i]n the United States in particular these interventions had a resounding effect on the life sciences. [...] The project of U.S. neoliberalism, I argue [...], is crucially concerned with the emergent possibilities of the life sciences and related disciplines” (Ibid., 3).

IP law acted as a central method for the financialisation of life’s potentiality in neoliberalism’s “ever-tighter alliance” between knowledge, the market, and capital. It thus worked for the market – but it also contributed to the structuring of the biotech sector and the promotion of certain research agendas over others. This introduced IP law to the informational-genetic conception of DNA – which resulted in the inevitable

adoption of the genetic-informational conception of life in the *Myriad* decision, even at the expense of some categories of patentability of isolated genetic sequences. But *Myriad*'s uneasy compromise ensuring the continued patentability of some genetic sequences also highlights the persisting relevance of IP for the creation of 'value' from life in the economy. It is argued in the last section of this chapter that IP's relationship with knowledge goes beyond this creation of value, encompassing the promotion of one form of scientific knowledge over other competing accounts of life.

Rouvroy finds that "[g]enetic reductionism is encouraged by the patentability of genes and gene sequences" (Rouvroy 2008, 41). This draws attention to the way in which IPRs act as an economic device that promotes the predominance and normalisation of genetic truth discourses, encouraged by the criteria of patentability. However, it neglects to point out that this patentability relied on a chemical-molecular understanding of genetics in IP law, and that this patentability was recently limited in the *Myriad* decision. This not only endangered value creation but also IP's contribution to the normalisation of an accepted canon of knowledge based on a predominant scientific paradigm. Genetic reductionism according to the "central dogma" understands the genetic code's function as the determining force within the organism instead of allowing for more complex interactions with environmental factors. This produces relatively predictable and stable accounts of the body and illness on the basis of the genetic code. A focus on the promotion of predictable knowledge and its connection to patentability highlights another facet of the *Myriad* decision: it continued to maintain some form of gene patents in the face of competing, more complex accounts of life – which would pose more serious problems for patentability and for questions of governing.

3. Competing Knowledges: Systemic Biology, Epigenetics and Synthetic Biology

The genetic-informational conception of life's challenge to the IP regime is highlighted even more when competing scientific accounts of life are considered. The recent developments in the *Myriad* case appear strangely out of step with developments in research paradigms of the life sciences. Here, a turn away from the reductionist genetic paradigm has taken place over the last twenty years (see for example Lock and Nguyen 2010, 330 ff., Lock 2005; H. Rose and Rose 2012; Landecker 2011; Braun 2007). Conceptions of life emphasising more complex interactions of genetic predispositions and the environment are becoming more

influential, as genetic determinism failed to fulfill the high expectations that it initially raised.

In particular, *epigenetics* and *systems biology* are competing ‘truths’ over life, which are undermining the predominance of the genetic determinist’ view in a power struggle between knowledges. The IP system cannot connect to these complex notions in the same way as to the genetic-reductionist paradigm – which was given “economic strength” in particular by the IP system’s previous chemical-molecular definition of genetics. It is argued that the delayed turn towards the informational-genetic view weakened this strength, while other scientific conceptions emphasising ‘complexity’ would certainly reduce it even more. While the patenting of aspects of genetic interactions (for example biomarkers, SNPs, HAPs) has been on the rise, there are some indications that the patenting of genetic sequences alone has been declining (see for example Mills and Tereskerz 2011, 712; Hopkins et al. 2007; Gaisser et al. 2009). The patenting of complex post-genomic interactions cannot be achieved in the same way, as this section explains. IP’s problematic relation to more complex accounts of life thus highlights the power exercised in the field of knowledge by the *Myriad* judgement’s turn to an informational-genetic concept, preferring and further normalising one ‘truth’ over other competing scientific knowledges.

3.1. New (old) truths: Systemic Biology and Epigenetics

IP law has only recently adopted the informational-genetic *dispositif*, which had been the determining force of developments over the course of the 20th century. However, in the life sciences, Francis Crick’s “central dogma” of the unidirectional mechanism of “DNA makes RNA makes protein makes us” (H. Rose and Rose 2012, 31) has been increasingly called into question. A recent resurgence of different approaches to life can be traced back to other fields of research that were side-lined when funding focused on the establishment of molecular biology by the Rockefeller Institute and other funding institutions (Kay 1993; 2000; H. Rose and Rose 2012, 66). This paradigm of molecular biology was promoted over and above any other contemporary scientific discourses, and drew funding away from competing programmes such as *systems biology*, which “was dealt a devastating blow when the Rockefeller Foundation, committed to a reductionist approach, rejected their proposal for a

research institute in Cambridge [...] in favour of a major investment in what was to become molecular biology” (H. Rose and Rose, *Ibid.*, 66).

Recently, systems biology has again drawn attention away from the ‘blueprint’ of life and focused instead on the overwhelming importance of complex interactions between biological systems and their environment. According to this school of thought, the potential for disease contained in the DNA code does not necessarily manifest itself in any case, only in particular circumstances – often depending on wider systemic factors. Rose finds that as “[a] genetic style of thought is giving way to a postgenomic emphasis on complexities (....) informational epistemologies seem to have reached their limit” (N. Rose 2007b, 47). Similarly, the field of *epigenetics* looks beyond the genetic code towards interactions with environmental factors for explanations of the emergence of particular conditions. Here,

“[g]enes are no longer thought of as acting independently but rather in constant interaction both with each other and with the multiple levels of the environment in which they are embedded. [...] DNA is no longer seen as an ‘informational macromolecule’ controlling the cell but rather as part of the web of molecules and their interactions that the cell employs during development.” (H. Rose and Rose 2012, 73; see also McAfee 2003, 204 f.)⁴⁶

The (re)emergence of epigenetics highlights the underlying assumptions built into the reductionist view of genetics. Rosenow terms this the “‘static-linear’ instead of ‘complex-dynamic’ understanding of life”, which “is inextricably bound to a particular episteme that assumes the sovereignty of the subject and the latter’s control over the world as object, and that is deeply at odds with the episteme that is advanced in significant strands of scientific complexity theory” (Rosenow 2012, 532; see also Wynne 2005, 70).⁴⁷ Braun also points to assumptions of control and sovereignty on the level of the bounded individual body containing molecular information. He

⁴⁶ For an introduction to epigenetics read for example: Carey (2012), Lewontin (2000); on the implications of epigenetics for our understanding of such commonplace things such as ‘food’ and the developmental origins of health and disease, see Landecker, who sets out a move away from understanding food in terms of energetical “conversion of matter” to “food as a form of molecular exposure” or food as “environment” (2011, 167).

⁴⁷ Rosenow focuses on the intersection of genetic conceptions of life and the biopolitical aim of securing the life and health of populations.

contrasts this view with that of the “post-genomic body” immersed in “a global economy of exchange and circulation, where the body is thrown into a chaotic and unpredictable molecular world filled with emergent yet unspecifiable risks” (Braun 2007, 7).

The informational-genetic conception of life thus accentuates predictability and control instead of focusing on the unpredictability and complexity characteristic of a novel and experimental research agenda (see Wynne 2005, 69). In the field of agriculture, studies conducted on the performance of transgenic crops provide an example of this imprecision and unpredictability, finding “patterns of mediocre and inconsistent crop performance and unpredicted effects that contrasts with the idealized image of agricultural genetic engineering as capable of increasing food production in an exact, ecologically safe, and economically sustainable manner” (McAfee 2003, 207). McAfee states that “[o]nly a narrowly molecular-genetic reductionist view, in which organisms are advanced Cartesian machines that can be understood by calculating the total of reactions among their molecules and atoms, would lead one to expect anything else” (Ibid., 209).

IP’s normalised scientific accounts emphasise predictability and control – in line with the IP regime’s need for stable patentable objects. Here, reductionist “negotiations” and processes of abstraction give rise to an “apparently stable object” (Calvert 2008, 385), thus concealing an inherent ambiguity of genetic conceptions of life (Pellizzoni 2011; Carolan 2008; 2010; Rosenow 2012, 534; McAfee 2003; Pottage 1998). Carolan points out “[t]here are no purified sequences of DNA in the world of genetic testing; no isolated protein-encoding DNA sequences in a field of engineered canola plants” (Carolan 2010, 122, he refers to the infamous Monsanto cases). Without the mental processes of abstraction needed to imagine the existence of isolated DNA sequences in a living plant in a field, patent enforcement against farmers’ use of seed material would be impossible. This “interpretive flexibility” is necessary for the maintenance of IP claims, however, “too much flexibility would [...] threaten the patent regime” (Ibid.).

IPRs on human genetic materials thus exert power through a “double reductionism” (McAfee 2003, 203), reducing scientific accounts of life to genetic code, and reducing the interactions and uncertainties contained in this evolving field of research to stable and predictable objects that can be traded in the economy.

Importantly, the *Myriad* decision maintains both these reductionist conceptions. Despite the limitation of patentability incurred by a turn towards informational-genetic conceptions of DNA, *Myriad* still continues the normalisation of genetic reductionist knowledge. In this way, the *Myriad* compromise governs scientific research paradigms in a way that supports the market and provides predictable knowledge for questions of governing life by preferring informational-reductionist knowledges to competing complex accounts. An opening towards more complex understandings of life could have profoundly unsettling effects on IP, resulting in a loss of stable and easily definable patentable entities – which would be even more difficult to negotiate and significantly complicate the circulation of value in the economy and the strategic use of genetic knowledge for the governing of life.

3.2. *Managing complexity: Biotech patents in danger?*

There are definite limits to the IP regime's potential for accommodating flexibility and complexity. Calvert analysed patents in the area of systems biology in comparison to the more traditional 'gene patent', finding that systems biology mainly relies on "computational techniques", without which "the interactions between biological molecules and the networks that result are far too complex to be analysed" (Calvert 2008, 386). In this area, Calvert has identified only two potential emerging strategies of patenting: "patents on networks of interacting molecules" which "have given rise to concern that patenting a whole system or network could have negative consequences for further research" and "patents [...] on computer-based models of biological systems [...] attempting to simulate disease and drug action *in silico*" (Ibid., 389 f., emphasis in original).

The IP regime is more successful in the broader area of *synthetic* biology, which for example "[tests] the models in systems biology by trying to build them as functioning biological systems" akin to "an engineering discipline" (Ibid., 391). Patents are issued on "complicated constructed networks and systems" but also on "functional and interchangeable parts (called 'biobricks')", which "often make a point of articulating their open source aspirations [...] not least because they explicitly attempt to make synthetic biology more similar to software code, which is modular,

standardized and re-usable” (Ibid., 392).⁴⁸ This shows an increasing convergence of IP in the life sciences with software IP⁴⁹ discourse, further enabled by the recent turn towards informational conceptions of ‘life’ in IP law. Thus *Myriad*’s turn towards information can be understood as intensifying the integration of several scientific fields, with potentially productive results for the economy – but also producing more tensions and possible challenges. The adoption of information as the central paradigm in this way contributes to the integration (or “flattening”) of “transnational circuits”: “[constructing] one of those level playing fields, in which standardized intellectual property regimes, forms of ethical governance, standards and regulations, and information allow distinct and widely separated economic actors to trade with one another” (N. Rose 2008a, 46).

The *Myriad* decision can thus be read as a significant power exercise that deepens economic exchange between different sectors of knowledge production and maintains the production of predictable accounts of life for the purposes of governing populations and individuals. However, this intensified integration and ‘flattening’ of circuits by rendering life in terms of information also leads to an intensification of reciprocal effects between information and the political sphere of life. Dillon and Reid argue that increased interconnections between information and life work to “(neo)liberalise” life, and “vitalise” order, thus increasing the influence of the politics of life and health on the economic and governmental order – and conversely, also increasing the influence of economic concerns on the politics of life (Dillon and Reid 2009, 21). This highlights the subversive potential of this integration, creating new pressures on existing regimes such as IP law to account for life and health of individuals and populations. At the same time, considerations of life and health are tied even more closely to an economic calculus, reinforcing a “cost-benefit” relation (see detailed explanation in Elbe 2009, 67).

This increased integration does however have the potential to significantly alter the relation of IP to conceptions of life. As information as such cannot be patented, an increase in complexity or increasing informationalisation could entail a future turn towards different forms of IP, such as copyright, method patents, and trade

⁴⁸ However, even open source agreements are a form of IP, as Calvert points out - they really are an open license.

⁴⁹ The potential for patents in the field of computer software is dwarfed by the issue of copyright. However, software patents are also possible. The “open source” movement is also much more influential in the software sector.

secrets. At the current juncture most of the actual transactions within the bioeconomy still rely on traditional reductionist representations of genomic science, as Rosenow points out (2012, 533). The *Myriad* judgement maintained this traditional paradigm in the patentability of cDNA, but nonetheless also directed future adjustments of the IP regime towards an informational definition of life, which may be more suitable for other forms of IP than the gene patent. This may cause changes in the use of IP, but also represents a complex process of accommodation of the IP system towards informational-genetic accounts of life – instead of an invalidation of IPRs by an opening towards more complex conceptions. This shows how the IP regime, by endorsing an informational conception, continued to exercise its role in the normalisation of predominant paradigms of knowledge. It continues to confer power-effects on an economically useful form of scientific knowledge, which very effectively traverses the field of science towards the economy and governmental decisions, integrating knowledge of the individual and the population within one code. This highly ‘economic’ form of knowledge is elevated by means of IPRs over more complex conceptions, which would be more difficult to integrate. While complexity is thus being kept at bay, IPRs continue to produce the certainty needed for economic circulation and decisions made on the proper governing of populations.

Conclusion

IP’s conception of life is undergoing change – but not for the purpose of an increased patentability of life. This chapter argued that a governmental perspective could show how changes in IP’s understanding of life from a chemical-molecular to an informational-genetic paradigm are triggered by the overwhelming influence of a genetic dispositif permeating the scientific and cultural domain. In response to this powerful influence, the *Myriad* judgement adjusted the IP system’s view of life towards the informational-genetic conception – while also ensuring the continued patentability of certain isolated forms of human genetic sequences (cDNA) by arguing that this still constitutes a ‘markedly different’ man-made substance, not predominantly determined by its informational content. This uneasy compromise accommodated the tension between the informational-genetic paradigm and the need to maintain patentability of some genetic sequences. In this way, IP jurisdiction became a tactics of governing for establishing the right disposition of things,

governing for the market and at the same time also contributing to the further normalisation of informational-genetic conceptions of life.

Normalised scientific knowledge is fundamental to a new art of governing. A governmental reading can emphasise IP's important role in bestowing 'power effects' on the predominant scientific paradigm, thus elevating it over other competing concepts. The *Myriad* decision also reveals the continued function of this normalising power contained in IPRs. By endorsing the informational-genetic paradigm, IPRs reduced patentability of genetic sequences in some contexts, but also pre-empted a move towards more complex accounts of life. This normalisation of informational concepts also governs for the market, in which clearly defined informational-genetic sequences can be more easily circulated than complex notions such as systems biology's interactions or epigenetics' contingent gene expressions. As the next chapter shows, this normalised genetic scientific knowledge has very profound implications for the identities of individuals, which are now governed with reference to this 'truth'. A new "somatic ethics" (N. Rose 2008a) takes shape around this truth, and individuals define their identity increasingly with reference to it. This new identity can also give rise to claims for access to the best treatment, or for greater participation in the use of IPRs. The influence of these new "genetic" subjects is already evident in the range of complainants and the kind of complaints brought against *Myriad*,⁵⁰ showing a growing concern with the ways in which IPRs are limiting the provision of healthcare, enabling or preventing the availability of tests and the communication of test results. This challenge to IP's relation to life will be analysed in the next chapter.

⁵⁰ Despite a wide range of claimants bringing the *Myriad* case to the level of the Supreme Court, only one claimant (Dr. Ostrer) was in the end decided to have legal standing in this IP dispute. This shows how IPRs continue to operate as a regime for exclusion in the *Myriad* case, as the next two chapters argue.

Chapter V Intellectual Property as a Regime for Exclusion – The challenge of ‘genetic subjects’

“My objective [...] has been to create a history of the different modes by which, in our culture, human beings are made subjects.” (Foucault 2000, 326)

The informational-genetic conception of life has had a pervasive influence on life beyond the immediate context of research and competition between scientific paradigms. On the level of the subject, it has given rise to “a new way of knowing yourself, apparently both enabling and obliging you to take control of your own biomedical destiny” (N. Rose 2008b, 424). As the last chapter already illustrated, the comprehensive influence of the genetic dispositif is giving rise to challenges to the IP regime’s relation to knowledge. This chapter takes the analysis of contestations around IPRs’ relation to genetic conceptions of life to the level of the subject. As access and control over genetic knowledge is becoming more fundamental to the formation of identities, subjects are increasingly encountering the IP regime as a limitation to their demands. These increasingly “active subjects” (Foucault 2000, 341), incited to assume responsibility for their health, are challenging the exclusion from the decision-making procedure where it comes to ‘their’ genetic conditions. In the case of *PXE International*, they are even patenting their condition. This counterintuitive use of IP against commercial aims, but rather for more altruistic control over research agendas has given rise to new IP strategies used by medical research charities in the national context and public-private-partnerships (PPPs) acting internationally.

This chapter proposes an analysis of IP’s role in their encounter with “genetic citizens” (N. Rose 2007b; Heath, Rapp, and Taussig 2004), which connects patients’ demands for new forms of participation with new responsibilities encouraging individuals to donate their tissue and their medical information to research projects. At this intersection of the individual and the bioeconomy, it is argued, IPRs govern the use of genetic knowledge by maintaining the exclusion of active patients’ influence from the bioeconomy and from exercising control over research programmes. A closer look at the distribution of rights and responsibilities in a “new

somatic ethics” based on genetic conceptions of life (N. Rose 2008a) shows how challenges to the exclusionary function of IPRs are being contained in a process of accommodation emphasising the contribution to research without granting greater influence on research agendas. This exclusion is also taking place in international debates on IP’s relation to global health programmes and to donors of genetic materials (see next chapter). However, as alternatives to IP are discussed in both contexts, this regime for exclusion may not succeed in the long run.

1. Patent Holders vs. Consumers – Challenging IP’s divisions

The IP system institutes a stark division between IP holders and consumers. It is usually only influenced by and developed further in specialist deliberations, which recognise in particular the opinions of national governments, representatives of international organisations, and pharmaceutical industry (on complex positions and conflicts in the industry, see Roemer-Mahler 2013). The individual is only afforded the option of being a patent holder or a consumer, as a license taker or the consumer of the end product. Patients or donors of genetic material are not usually considered in IP law.⁵¹ Their contribution to patents on genetic information typically ends with the donation of materials and information, as the case of biobanks shows: here, control over the range of license takers and thus over who can use genetic information derived from the donations is not within the remit of the patient’s or donor’s power. But cases such as *PXE International* show how patients with specific genetic conditions are increasingly contesting this division by for example becoming both patent holders and patients. This growing influence of patients is also recognised by the biotech industry, which relied on patients as advocates for the ‘*No Patents, No Cure*’ campaign in favour of the EU’s Biotech Directive on the patentability of genetic information.

At the same time, patients are increasingly encouraged to contribute to ‘research’ by donating tissue (see below), which creates new responsibilities and draws further attention to the lack of influence on the type of research being conducted these samples. This situation is only directly addressed by projects of *citizens’ science*. The uBiome biobank project for example promises a “revolution”

⁵¹ Only the EU Biotech Directive mentions a range of different subjects in its preamble, such as donors of genetic material and farmers.

by opening up decisions on experiments.⁵² This section gives a brief overview of challenges to the entrenched division between patent holders and patients, highlighting how patients have begun to use IPRs to exert control over the type of research done with the genetic material and information. The example of *PXE International* shows how an under-researched condition gave rise to an initiative of patients acting as patent holders, patenting the genetic sequence of their condition (*pseudoxanthoma elasticum*, or PXE) and thus exerting control over the research agenda in this very specific area. However, this approach only overcomes the exclusion of the individual from the ‘professional’ realm of patent holders and researchers by joining them – which is only possible in an economic context where the patients in question have the financial means to take out a patent in the first place.⁵³ But *PXE International* and the example of Medical Research Charities (MRCs) illustrate a different use of IPRs. These entities prioritise different areas and methods of research to those chosen by the industry’s research and development (R&D) model, highlighting that IP’s confrontation with genetic subjects could not only challenge the parameters of IP’s participatory process, but also give rise to entirely different approaches to the financing of R&D.

1.1. IP holders and consumers/patients – The subjects of the IP regime

IP law’s general view of patients and donors of genetic materials is one of fundamental disconnection. This has been made remarkably clear in the landmark case of *John Moore v Board of Regents of the University of California* (1990) 51 Cal. 3d 120; 793P.2d 479⁵⁴. John Moore underwent treatment for hairy cell leukaemia including the removal of his spleen, after which cancer cells from the spleen were developed into cell lines and patented by his doctors without his knowledge. Between 1976 and 1983 he was repeatedly asked to return to the hospital for further tests, and each time provided further samples of blood serum, skin, bone marrow and sperm –

⁵² They promise: “We’ll also crowdsource our research questions: you will be able to design your own experiments” (uBiome 2013).

⁵³ This also shows that ‘biological citizenship’ can only really occur in a certain economic and geographical contexts. On the international level for example the argument of ‘market failure’ seeks to address international economic and health inequality, as the next chapter will point out. Selmeczi (2009) points out that biopolitical notions always already contain an element of abandonment, as the concept of the ‘population’ always excludes segments of society, especially on the international level. About general problems incurred in ‘upscaling’ Foucault’s ideas to the international, see debate between Kiersey, Rosenow & Weidner (2010) and Chandler (2010), discussed in chapter III.

⁵⁴ Available at http://www.eejlaw.com/materials/Moore_v_Regents_T08.pdf (accessed 14.1.2012).

this additional information was instrumental for the successful exploitation of the potential of the cell line. Eventually, when his doctor asked him to sign a broad consent form, which would have transferred “all rights” in “any cell line or any other potential product which might be developed from the blood and/or bone marrow obtained” (Skloot 2011, 228), Moore discovered that his doctors had already registered a patent on information derived from his cancer sequence – called ‘Mo’.⁵⁵

The Supreme Court of California ruled that Moore had no rights to either a share of the profits made from the use of his sequence, or for damages. The Court determined that the patient’s reasonable concerns were covered by the ideas of informed consent and fiduciary duty, which had been breached in this case, but did not entitle Moore to a share in the profits. Importantly, the cell-line itself was not considered Moore’s property, for “the patented cell line is both factually and legally distinct from the cells taken from Moore’s body” (*Moore v Board of Regents* at p. 12; see also previous chapter), and there is no precedent that holds “that a person retains a sufficient interest in excised cells to support a cause of action for conversion” (at p. 7).⁵⁶ According to the court, a decision in Moore’s favour would have had far-reaching detrimental effects, effectively “hinder[ing] research by restricting access to the necessary raw materials” and “threaten[ing] with disabling civil liability innocent parties who are engaged in socially useful activities” such as research (at p. 15).

Judge Arabian’s concurring opinion goes even further in his condemnation of Moore’s demands for a share of the profit:

“Plaintiff has asked us to recognize and enforce a right to sell one’s own body tissue *for profit*. He entreats us to regard the human vessel – the single most venerated and protected subject in any civilized society – as equal with the basest commercial commodity. He urges us to commingle the sacred with the profane.” (at p. 19, emphasis in original)

⁵⁵ This designation is highly reminiscent of Henrietta Lacks’ treatment, and the resulting ‘HeLa’ immortal cell line (see Skloot 2011).

⁵⁶ Conversion is “a tort that protects against interference with possessory and ownership interests in personal property” (at p. 5) – and the main claim in Moore’s complaint. In this the court brushed aside the Court of Appeal’s application of *Venner v. State* (1976) 30 Md.App. 599 [354 A.2d 483], which found that “[i]t is not unknown for a person to assert a continuing right of ownership, dominion, or control, for good reason or for no reason, over such things as excrement, fluid waste, secretions, hair, fingernails, toenails, blood, and organs or other parts of the body (...)” (354 A.2d at p. 498; quoted after *Moore v Board of Regents*, p. 9 Footnote 28).

The IP regime's view of the isolated cell line as entirely separate to the human body (see previous chapter) is, however, not considered to “commingle the sacred with the profane” in a similar manner.

This highlights an entrenched legal ‘truth’ regarding the nature of isolated genetic sequences, and a complete dismissal of the patient's continued interest in the use of this information for the purpose of ‘research’. The patient's rights are only comprised of fiduciary duty and informed consent, and the commercial realm in which research is conducted and patents are registered is completely beyond the patient's reach. It is clearly stated that high hurdles enforcing standards of accountability and legitimacy are against society's interest in research. This effectively means that, due to the highly unpredictable content of future research using genetic information, patients are most likely faced with a yes/no decision at the level of informed consent to their treatment and all further use of the tissue and the information taken from this tissue – as even the example of UK Biobank's more complex consent form shows (UK Biobank 2011, see below). Volunteer participants in the recently completed UK Biobank had the opportunity to consent to some tests and refrain from participation in others – but the transfer of IP rights on the material and the resultant information is final.⁵⁷ The patient/donor is thus prevented by the patenting process from exerting influence on the use of IP derived from the donation.

1.2. Patients as Patent Holders: The case of PXE International

The controversial dichotomy of the patent holder and the patient/donor has been challenged especially with regards to influence on the future use of IP, where control over types of research can be exerted for example through the licensing process. In one of the most instructive examples of this type of influence, patients became patent holders to their ‘own’ genetic condition, thus directing the type of research conducted on this condition. *PXE International* is a non-profit organisation formed by Patrick and Sharon Terry in 1995, whose two children are PXE patients. PXE International consists amongst other things of a specialist PXE International Blood and Tissue

⁵⁷ UK Biobank consent form states: “I [...] relinquish all rights to these samples which I am donating to UK Biobank” (UK Biobank 2011). This complete transfer of IPRs remains a standard even in open source biobanks such as the Personal Genome Project. Their consent form states: “Any tissue samples or specimens that you provide to the PGP as part of your participation in this study, including saliva, hair, blood or other biological tissues, are the property of and are owned by the PGP and not by you [...]” (Personal Genome Project 2012, 18).

Bank, which “accelerated the discovery of the gene associated with PXE” and led to a patent being issued on this sequence in the US in 2004 (PXE International 2015a). Since then, PXE International “steward[s] the intellectual property to equitably advance products and services around the world for the individuals and families living with PXE”, and has become “a role model for many other groups throughout the world” (PXE International 2015b).⁵⁸ Their use of IP as part of their research strategy has been adopted by other organisations focussing on particular genetic conditions, and also larger scale organisations such as Medical Research Charities (see below). Here IPRs are specifically used for the improvement of health of others patients, “ensuring both open access to the gene for all researchers, and preventing royalty fees that might increase the costs to any individual seeking testing for PXE” (Heath, Rapp, and Taussig 2004, 164).

Paradoxically, IP is used here in order to guarantee access to genetic information. Waldby and Mitchell argue that “the Terrys have appropriated the commodity form (in this case a patented gene) to create new flows of body tissues and information”, which “are patient-oriented (not doctor- or corporation-oriented), in that they seek to create a worldwide patient rights community” (Waldby and Mitchell 2006, 154). Benefits of this approach are “allow[ing] PXE International to have access to venture capital in ways that were not otherwise possible” and ensuring “continuing flexibility” towards licensing of these patents (Ibid., 154 and 155). Perplexingly for an example of “commodification”,

“[o]n the one hand, this approach seems to privilege a neoliberal model of competing groups of “stakeholders,” who circulate tissues and information within their groups but jealously guard against “free” dissemination to outsiders, [...] [o]n the other hand [...] this approach [...] does not treat people as resources to be “mined” but instead includes them within the informational flows normally accessible only to researchers and corporations” (Ibid., 155).

Dickenson points out that this approach “suggest[s] a possible middle way between pure altruism and pure capitalism” (2013, 188). This thesis argues that the surprising

⁵⁸ For the way in which the Terrys are providing their support to other organisations see Heath, Rapp & Taussig (2004, 164).

use of a commodity without the expected exploitative results on patients or donors, but instead with the result of an increased inclusion of people into the area of research and pharmaceutical drug development becomes more plausible when looked at from the perspective of a new “somatic ethics” (N. Rose 2008a) instructing patients to take increased responsibility for their own health, especially with regards to knowing their genetic predispositions (see below). IP law is being used here for the purpose of governing genetic life by patients and for the benefit of patients.

This new responsibility and the influence of genetic knowledge on identity formation become obvious in statements such as “*Your DNA. Your Health.*” or “*Your DNA is the biggest influence in your life!*” – in this case advertising the (now defunct) services of personal genomics firm *decodeme*.⁵⁹ Similar claims made by a competitor, *23andMe*, gave rise to a ban on health-related genetic reports pending market authorization for medical devices by the US Food and Drug Administration (FDA). The FDA’s concerns about “the potential health consequences that could result from false positive or false negative assessments” (FDA 2013) show how seriously the results of these genetic scans are taken – and how they can lead to very serious decisions on behalf of the newly diagnosed “pre-symptomatic ill” patients (Wehling 2011, 234). Importantly, this knowledge also generates pressure on policy-makers, as patients demand existing regimes to change and to have greater access to testing and potential treatment. Instead of focusing on commodification, this thesis argues that these challenges can be better understood as an emerging biological or genetic citizenship (N. Rose 2007b; Heath, Rapp, and Taussig 2004), which is produced by genetic knowledge of life and health. This chapter turns to a closer look at IP’s relation to the emergence of new rights and responsibilities surrounding genetic conceptions of life after briefly setting out how especially collective legal subjects such as medical research charities are challenging IP’s exclusionary function, and patients groups are becoming involved in campaigns for the promotion of pro-IP legislation.

⁵⁹ See www.decodeme.com (accessed 5.11.2012). These personal genomics services are no longer offered by this company. A competing personal genomics company, *23andMe*, also had to withdraw its health-related genetic reports after severe criticism by the US Food and Drug Administration (FDA) in November 2013 (FDA 2013; 2014). It has since begun trading in the UK, offering testing kits for personal genome analysis and health reports that are no longer available in the US (23andMe 2015a; 23andMe 2015b).

1.3. Patient groups and Medical Research Charities: The increasing influence of patients' opinions

A variety of collective legal subjects are increasing the influence of patients by strategically using IP for the promotion of research in particular genetic conditions. In the case of medical research charities, universities or research institutions (i.e. artificial legal or *juridical* subjects) hold patents for genetic conditions, but actively involve patients in decisions on their terms of use. One example is Cystic Fibrosis, where the University of Michigan, Johns Hopkins University, and the Hospital for Sick Children hold key patents (Chandrasekharan, Heaney, et al. 2010, S194). These patents have at times limited access to testing for the condition, as Chandrasekharan points out, “[t]he Cystic Fibrosis Foundation has been engaged in licensing decisions, making cystic fibrosis a model of collaborative and cooperative patenting and licensing practice” (Ibid.). As a result of involving patient representatives in the licensing process, patient’s concerns for access to tests and potential treatments have in these cases outweighed any interest in profit.

Other research collaborations on genetic conditions have been operating in a similar manner, patenting genetic information on ‘long QT Syndrome’ (Angrist et al. 2010), Hereditary Hemochromatosis (Chandrasekharan, Pitlick, et al. 2010), Tay-Sachs and Canavan Disease (Colaianni, Chandrasekharan, and Cook-Deegan 2010). It was shown that active patent enforcement against competing providers of tests limited access to tests (Angrist et al. 2010, S111), and high costs also deterred patients (Powell, Chandrasekharan, and Cook-Deegan 2010). Another cautionary example is the patent registered by the hospital on the genetic sequence and testing methods for Canavan disease, which came as a complete surprise to the charity and families contributing information and samples to this research (Dickenson 2013, 191 f.). This shows that the exclusionary effects of IPRs are not automatically counteracted in all these models. Evans argues that

“harms are most clearly seen when an exclusive (or no) license is issued by a patent holder, resulting in only a single laboratory that is allowed to perform a given test. In such circumstances, patient access to testing can suffer, most clearly when exclusive providers fail to contract with insurers such as state Medicaid programs, leaving patients without the option of a given genetic test should it be

recommended by their provider. Other harms of exclusivity include an inability to obtain second-opinion testing and concerns over quality, given that the most robust means of quality assurance are not available in the context of a single provider.” (J. P. Evans 2010, S3)

High costs for tests continue to cause controversy, and are challenged by patients, as in the case brought against *Myriad Genetics* and the very strict enforcement of their patents on breast cancer markers BRCA1 and BRCA 2 (see facts in Gold and Carbone 2010; also see discussion in previous chapter). Their IP strategy disregarded patient’s interests completely – and led to a collective legal challenge brought by patients, doctors, and the American Civil Liberties Union to “take back our genes” (ACLU 2013).

The influence of patients in the Cystic Fibrosis Foundation ensured a form of access to testing that was more in line with patients’ needs and thus placed access to testing before market exclusivity. Their involvement fell short of actual IP ownership, and thus did not amount to outright autonomous control over decisions as in the case of PXE International. However, it shows that the influence of patients can change the priorities of IP strategies – but not always in the same way and for the same purpose. The biotech industry has also noted the increasing influence of patients and has turned to patient groups for added legitimacy for example in their “No Patents, No Cure” lobbying campaign for the European Biotech Directive 98/44/EC on extending patenting to the biotech sector (1998).

The inclusion of patient groups came as a response to the negative result of the initial vote in the European Parliament in 1995, which came as a shock to the industry. Debate and public opinion at the time in Europe was very critical of the notion of ‘patenting life’ and was not in favour of extending IP to information derived from human genetic materials. The industry’s response to this debacle was to fight “fire with fire”⁶⁰:

“Faced with such an onslaught, the industry hired a British lobbyist, Paul Adamson, who met with patients' groups and helped persuade 30 terminally ill patients in wheelchairs - people likely to benefit from

⁶⁰ SmithKline Beecham alone reportedly allocated 30 million Euros for a broad “pro-Directive Campaign” (Calvert and Joly 2011, 9; Corporate European Observer 1998).

biotechnology research - to greet members of the Parliament on the days of crucial votes on the legislation. The patients wore bright yellow T-shirts painted with the slogan "Patents for Life" and chanted, "No Patents, No Cure!" It worked. Three years after it was first rejected, the Life Patent Directive passed, 432 to 78, in a final vote in May 1998." (Bilefsky 2005)

This marked a turnaround in PR strategy, turning the opposition's slogan "No Patents on Life" on its head. It also clearly acknowledged and operationalised the increasing influence of patients (see Calvert and Joly 2011) – albeit as a means for increasing the reach of the IP regime.

Calvert and Joly argue that the involvement of patients made the "No Patents, No Cure" strategy particularly effective: "[patient charities and organizations] were by far the most influential lobby groups in respect to the Directive. Many Members of the European Parliament voted in favour of the Directive under strong pressure from these interest groups in what was described as 'the largest lobby campaign in the history of the EU'" (Ibid., 9). The industry has since then tied the demands of patients into their legitimization of IPRs:

"Protecting intellectual property rights is essential to encourage research and development, leading to new and better medicines. Only with effective patent laws can we continue to bring therapeutic improvements to patients, ultimately resulting in better patient care."
(Novartis 2015)

But Calvert and Joly also point to the way in which these patient groups were "manipulated" by the industry (Calvert and Joly 2011, 9).⁶¹ Connections between the pharmaceutical industry and patients groups for lobbying purposes such as the "No Patents, No Cure" campaign are often suspected of being instances of 'astroturfing' – a term which denotes the use of artificially created 'grassroots' movements. More recently, the pharmaceutical industry's deployment of patients' influence has been

⁶¹ A Greenpeace report claims that "It was later disclosed that the lobbyists, who claimed to be speaking in the name of European patients, were in fact paid by the pharmaceutical industry and had no mandate from the patient organisations they purported to represent to lobby in favour of the patent directive" (Schweiger 1999), also claimed by Scullion (2002).

criticised as the industry “mobilised” patients in support of their bid *against* new rules requiring the disclosure of trial data (Sample 2013).⁶²

Nevertheless, the pharmaceutical industry’s strategic use of patients acknowledges the increasing influence of patients. This chapter argues that patients’ demands for increased involvement in the direction of research and development are part of a wider challenge to IP based on genetic conceptions of life. From this perspective, these examples can be read as instances of active participation of patient groups demanding their rights as “biological citizens” (N. Rose 2007b; Heath, Rapp, and Taussig 2004). But the industry’s campaign for an extension of the patentability of ‘life’ shows that patients’ involvement in IP strategies is more complex than this concept suggests. It rather points out that a “new somatic ethics” (N. Rose 2007a; 2008a) based on genetic conceptions of life consists of rights *and* responsibilities conducting the conduct of patients. A closer analysis of IP’s confrontation with genetic subjects shows the emergence of patients’ responsibility to contribute to research, which is not matched by an equal increase of participatory rights. IP thus responds to challenges as a regime for exclusion, which “governs” the division between donations and further use of samples. The next chapter then argues that this function of IPRs can also be traced within international debates on the relation of IP to life, where “a new moral economy of R&D” for example emphasises notions of sharing in drug development projects (Lezaun and Montgomery 2015, 5).

2. ‘Producing’ Subjects – The Genetic Dispositif and the Somatic Ethics of “Genetic Citizens”

The increasingly complex influence of patients on the use of IP can be better understood as a result of biopower’s productive relation between truth discourses about life and modes of subjectification (Rabinow and Rose 2006; Foucault 2000).⁶³ Foucault repeatedly stressed the constitutive relation of truth discourses to subject’s identities, which the subject’s individual conduct in turn validated and reinforced:

⁶² Clinical trial data (regarding side-effects and failed trials) is not routinely disclosed, even after gaining market approval – which can have serious adverse effects on public health (see argument for disclosure in Goldacre 2012). The industry argues trial data should be covered as a form of ‘trade secret’ – which constitutes a separate category of IP and is becoming an important areas of IP policy making internationally.

⁶³ Modes of Subjectification are also sometimes termed modes of objectification or modes of subjectivation (Butler 2005). For more background on the concept of subjectification, see for example discussion in Odysseos (2011), Edkins (1999), Butler (2010, first published 1989).

“This form of power that applies itself to immediate everyday life categorizes the individual, marks him by his own individuality, attaches him to his own identity, imposes a law of truth on him that he must recognize and others have to recognize in him. It is a form of power that makes individuals subjects” (Foucault, *Ibid.*, 331). This section first explores the parameters of processes of subjectification, and then looks at the production of *biological* or *genetic* subjects, which arguably emerge on the basis of genetic knowledge over life.

2.1. The ‘conduct of conduct’ and the making of the genetic subject

Analyses of governmentality look at the constitution of the subject as a part of the reproduction of relations of power. This raises questions about the relation between norms for the conduct of the individual and the subject’s freedom of action within governmentality. Rose, O’Malley & Valverde draw attention to the particular connection between “techniques of the self”, freedom, and forms of governmentality:

“[...] technologies of the self were formed alongside the technologies of domination such as discipline. The subjects so created would produce the ends of government by fulfilling themselves rather than being merely obedient, and in Rose’s phrase (Rose 1989) would be obliged to be free in specific ways.” (N. Rose, O’Malley, and Valverde 2006, 89)

This highlights the way in which the ‘fulfillment’ of the self becomes conducive to the maintenance of governmental goals, incited by processes that “govern at a distance” (Miller and Rose 1992) through “regulated self-responsibility” (McNay 2009, 62).⁶⁴ As Foucault points out, the analysis of governmentality is fundamentally concerned with “the way in which one conducts the conduct of men” (Foucault 2008, 186) – showing how power is exercised in order to produce subjects that are “open and amenable to governmental interventions and techniques” (Odysseos 2011, 445). The economic subject, *homo oeconomicus*, constitutes “the interface of government and the individual” in governmentality (Foucault 2008, 253), and is an “entrepreneur

⁶⁴ McNay sets out that “[Foucault’s] idea of self as enterprise [...] understands the commodification of subjective experience not so much through ideas of passive consumerism, standardization and heteronomy, as through ideas of active differentiation, regulated self-responsibility and depoliticized autonomy” (McNay 2009, 62).

of himself, being for himself his own capital, being for himself his own producer, being for himself the source of [his] earnings” (Ibid., 226). This individualisation of the subject and the transfer of responsibility to this individual for conducting itself in a responsible, approved (or ‘normal’) manner is a marker of a specifically neoliberal form of governmentality, as McNay points out. The transfer of responsibility to the individual gives rise to the notion of the “self as enterprise” (McNay 2009).

Foucault points out that, besides participation in the economy, governing increasingly takes the health and well-being of the population as its aim, and the conduct of conduct on the level of populations is increasingly fostered and directed accordingly (in the “population-biological processes-regulatory mechanisms-State” series of “biopolitics”, Foucault 1997, 250; see also Foucault 1978, 139). In this conduct, “maintenance of the healthy body became central to the self management of many individuals and families” (N. Rose 2007a, 4). Responsible patients were

“[e]ncouraged by health educators to take an active interest in their own health, and ‘activated’ by the new cultures of active citizenship, many refused to remain merely ‘passive’ recipients of medical expertise. ‘Patients’ became ‘consumers’ actively choosing, and using medicine, biosciences, pharmaceuticals and ‘alternative medicine’ in order [*sic*] maximize and enhance their own vitality, demanding information from their doctors, expecting successful therapies, and liable to complain or even go to law if they are disappointed.” (Ibid., 11)

This process is not one of unidirectional domination, but rather a diffuse exercise of power that has the potential to sustain and also to challenge existing regimes. Within governmental networks, Miller and Rose point out that “[e]ach actor, each locale, is the point of intersection between forces, and hence a point of potential resistance to any one way of thinking and acting, or a point of organization and promulgation of a different or oppositional programme” (N. Rose and Miller 2010, 208, first published 1992). While the exercise of power makes individuals into subjects, this does not necessarily imply a top-down imposition of a normalising strategy on the individual by the state: “biopower [...] [was] consentingly invoked by many social groups [...].

The health of all [...] became a priority of all” (Elbe 2005, 407). Normalising power is thus exercised by various actors, including the individual or “active” citizen, and always contains the potential for a subversion of existing power relations.

But the power of active patients to challenge healthcare provisions in order to enhance their vitality is also accompanied by emerging responsibilities. Rose argues that the conduct of “active patients” is conducted by a “new somatic ethics” governing the political sphere of life and health, which shares an “elective affinity” with the bioeconomy (N. Rose 2007a; 2008a). The previous chapter of this thesis argued that the operation of this elective affinity could be traced in IP’s production of truth discourses of ‘life’, which normalised the informational-genetic view of life (the genetic *dispositif*) at the expense of other more complex accounts of ‘life’. This informational-genetic conception combines knowledge of the individual and the population in one code, which enables the integration of this information into the bioeconomy. This chapter argues that this genetic *dispositif* influences the formation of identities, conducting the conduct of subjects according to genetic ‘truths’ in a new somatic ethics, which also transfers healthcare responsibilities onto the subject. The increasing integration of genetic information into the bioeconomy further intensifies the exposure of the subject to this truth – thus amplifying the tensions between exclusive IPRs and new rights and responsibilities of ‘active patients’. Before this chapter turns to an exploration of IP’s role in the maintenance of the division between patent holders and patients/donors, the next section sets out new rights and responsibilities affecting the conduct of “active patients” in a “new somatic ethics”.

2.2. *New Rights and Responsibilities: ‘Genetic’ Citizens and Somatic Ethics*

The shift of life to the genetic level has profoundly affected the identity of the individual and given rise to new rights and responsibilities on the basis of this ‘truth’.⁶⁵ It is argued here that this pervasive influence of genetic knowledge on the conduct of conduct goes far beyond Foucault’s brief problematisation of the use of genetics in “the control, screening, and improvement of the human capital of individuals, as a function of [...] reproduction” (Foucault 2008, 228 f.). Rather than this deterministic scenario of selective reproduction, the far less clear-cut

⁶⁵ The reach of these rights and responsibilities does not extend to all participants of society, and surely not to all humans world-wide (see critique in Selmeczi 2009). It is rather mostly limited to influential segments of Western societies. For the implications of IP’s exclusionary function on the international level, see next chapter.

interpretation of genetic risks has led to the emergence of the “pre-symptomatic ill” (Wehling 2011, 234). It also enfolded the individual in a new somatic ethics setting out the conduct of responsible patients, in which “[h]uman beings identify and interpret much of their unease in terms of the health, vitality, and morbidity of their bodies; they judge and act upon their soma in their attempts to make themselves not just physically better, but also to make themselves better persons” (N. Rose 2008a, 46). The active patient is incited to know and improve his/her health according to this new “law of truth” (Foucault 2000, 331) – and through this is arguably becoming a biological or genetic citizen, whose demands for better medical treatment wield biopower (N. Rose 2007b; Heath, Rapp, and Taussig 2004). This biopower challenges existing healthcare regimes, and also IP’s exclusive assignment of ownership over genetic knowledge, but it is also being limited by IP’s continuing maintenance of divisions between patent holders and patients.

The “molecularisation” of life (see for example Novas and Rose 2000) shifts the understanding of the ‘nature’ of the subject to a different level, marking a shift of the medical gaze similar to the change in the eighteenth century (see N. Rose 2007b, 4 f.), changing “[n]ot only the names of diseases, not only the grouping of systems were not the same; but the fundamental perceptual codes that were applied to patients’ bodies” (Foucault 1963, 64). Novas & Rose term these molecularised concepts of life and of disease a “new ‘molecular optics’” (2000, 48), while Heath, Rapp & Taussig refer to the development of new forms of self-understanding of the individual, adapting to the new ‘truth’ about his/her medical destiny contained in his/her genetic code as “a genetic ‘micro-anatomo-politics’” (2004, 154). Importantly, Novas and Rose point out that “[t]hese developments [...] re-shape the ways in which we are governed, and the ways in which we govern ourselves”, “creat[ing] an obligation to act in the present in relation to the potential futures that now come into view” (Novas and Rose 2000, 486).

This obligation to act in the present according to the demands of potential futures “come[s] into an association with all the other shifts that are assembling somatic individuality, with the norms of enterprising, self-actualizing, responsible personhood that characterize ‘advanced liberal’ societies” (Ibid., 488). Subjects are thus incited to operate with reference to these connected identities (or modes of subjectification) of the genetic and enterprising individual. In contrast with Novas and Rose’s focus on the individual, Raman and Tutton stress that the influence of the life

sciences does not only amount to a ‘disciplining’ of the individual’s conduct, but still remains connected to knowledge generated at the level of the population (Raman and Tutton 2010, 721). Critiquing notions of a wholesale transformation of Foucault’s “old biopolitics from above” to a “new biopolitics from below”, they argue that “truth discourses about life contain a hybrid of molecular and population categories” (Ibid., 722). Thus “old” and “new” modes of biopolitics coexist in the molecular age, giving rise to population-based governmental interventions such as national biobanks and “strategies for infection control”, as well as a new “pastoral or enabling” role of the state (Ibid.).

At the heart of a new biopolitics “from below”, the concept of biological citizenship (or genetic citizenship)⁶⁶ encapsulates the rights claimed by the active patient within this new somatic ethics. Based on the biological condition of the entrepreneur of the self, these rights have the potential to challenge governance and health providers, “[articulating] claims to participation in social and political life and to the recognition of certain individuals’ or groups’ identities, expertise and specific needs based on their (supposedly) biological or genetic conditions” (Wehling 2011, 225).⁶⁷ In particular, “these practices challenge conventional notions of a divide between lay people and experts” (Heath, Rapp, and Taussig 2004, 152). While Novas (2006) and Rose (2007b) respectively emphasise the power of ‘hope’ in generating demands made by patients and patient organisations, Wehling cautions against overstatements in this direction by drawing attention to the contrast between new demands and the amount of new responsibilities imposed on the individual “to optimize ‘healthy’ bodies and minds” (Wehling 2011, 227).

The clearest examples of biological citizens are for instance patient groups, which are formed around a common genetic condition (such as Huntington’s disease or PXE). These patient groups can organise support for their condition more effectively and make more successful demands for research on that condition than any individual patient would be able to make. They can liaise with pharmaceutical companies and serve as research repositories for them, which also can improve the amount of research done with regards to their particular condition. Patients of more complex diseases such as arthritis and diabetes are also increasingly organising in this

⁶⁶ Genetic citizenship is the term used by Heath, Rapp and Taussig (2004). In this thesis both ideas will be referred to interchangeably, with the predominant focus on their conception of rights and responsibilities of the individual in a new somatic ethics based on the molecularised view of ‘life’.

⁶⁷ Wehling provides a comprehensive overview and critical evaluation of the concept (2011).

way (Heath, Rapp, and Taussig 2004, 159). At its most successful point, this activation of patients has the potential to radically reverse the roles between experts and patients, as Novas & Rose find: “the ill patients themselves, those ‘asymptomatically ill’ and their families [...] are increasingly demanding control over the practices linked to their own health, seeking multiple forms of expert and non-expert advice in devising their life strategies, and asking of medics that they act as the servants and not the masters of this process” (Novas and Rose 2000, 490).⁶⁸ However, this radical potential is limited by the simultaneously increasing moral duties of the individual, as Wehling points out.

Most critically, the mobilising influence of hope for new treatments further essentialises conceptions of ‘good’ patients, which actively participate in pharmaceutical trials and the formation of biobanks etc., and thus are contributing to the generation of knowledge – but also of economic value. In particular,

“deeply emotional representations of the fears and hopes of sufferers, and their expectations that new medical technologies will deliver them from their suffering, structure many popular representations of patients and their illnesses, and are often deployed by medical charities, support groups and others in seeking to raise funds to keep that hope alive.” (N. Rose 2007b, 136, quoting from Nik Brown)

The power of hope thus not only gives rise to biopolitical challenges, but also engenders subjectivities that contribute to the production of economic value. The invocation of the power of biological citizens is in this way tempered by an “‘elective affinity’ between the spirit of biocapital and our contemporary somatic ethic” (N. Rose 2007a, 5).

The remainder of this chapter argues that IP is central to the management of this “elective affinity” and contributes to the governing of demands made by patients by maintaining a division between the realm of economic relations and the biopolitical challenge of active patients. This exclusionary function prevents the

⁶⁸ An interesting example for the power of such demands is the campaigning of DEBRA (the Dystrophic Epidermolysis Bullosa Research Association), which sees “‘parents [use] their bloody, blistering babies like a battering ram’ to capture Congressional attention” (Heath, Rapp, and Taussig 2004, 155). In this case, “‘babies’ bodies [breach] the boundaries between home, state, and civil society” (Ibid.), creating a strong motivation amongst politicians for helping the afflicted.

bioeconomy from being affected by a potentially radical role reversal between patients and experts. The next section of this chapter shows how the IP regime maintains a separate sphere of (bio)economic value by structuring the participation of active patients (or biological citizens) in this area. While alternative models of participation are explored in examples of citizens' science, an analysis of debates around participation by "research patients" or "research citizens" shows how the demands of genetic citizens are being controlled. While patients are increasingly incited to fulfil a new responsibility of voluntary participation in trials and research, the bioeconomy still functions by remaining largely closed off from decisive influence exerted by patients on the use of donated materials in Rose's "transnational circuits of vitality" (N. Rose 2008a, 46). This management of biopolitical challenges "from below" (Raman and Tutton 2010, 722) is then also traced in emerging challenges to the exclusionary function of IP in an international version of a "new moral economy of R&D" (Lezaun and Montgomery 2015, 5) – representing an international version of the "biopolitics from above".

3. 'Genetic Citizens' or 'Research Patients'? – IPRs as a *regime for exclusion* of challenges from a 'new biopolitics from below'

Anne Kerr (2003a; 2003b) provides a more complex understanding of the rights and responsibilities of "genetic citizenship", emphasising in particular the continuing means of exclusion of individuals from the decisions made in research and medical treatment. Looking at modes of participation in biobanks, Kerr highlights the pivotal role of experts in maintaining this exclusion – while patients' "responsibilities for self-education and self-surveillance" are increasing (Kerr 2003b Ibid., 221). Wehling also emphasises "undesirable consequences and new forms of stigmatization or even exclusion" caused by the "biologization or geneticisation of rights, responsibilities" (Wehling 2011, 240). Their critical reflections on the actual rights and responsibilities of subjects in a new somatic ethics show continuing restrictions to participation encountered by the 'empowered' active patient of the new molecular biopolitics from below (see previous section). This section argues that IPRs are instrumental to the maintenance of the division between biological citizens and experts. In the example of large-scale biobank projects, IPRs are shown to work as a regime for exclusion maintaining limits to participation. These large-scale projects are then contrasted with alternative approaches to IP in examples of citizens' science. However, while these

appear to challenge the distribution of rights and responsibilities, at closer inspection, they are even more dependent on and instrumental in the perpetuation of responsibilities contained in a new somatic ethics. The IP regime thus engages with and governs demands for patients' participatory rights by structuring entirely separate spheres of influence.

3.1. IPRs' role in the division between citizens and experts

Kerr points out that rights *and* obligations are already contained within the concept of citizenship, understanding "citizenship as a set of inter-linked processes of inclusion and exclusion of individuals based on the allocation of entitlements, obligations and immunities, which depend upon notions of their contribution to society" (Kerr 2003a, 45). However, participatory rights are not the same for experts and citizens. Experts are involved in patients' decision-making on the personal level (with regards to genetic testing or participation in biobanks) and also contribute to policy-making. In contrast, patients or citizens "are not considered to be sufficiently competent to make a significant contribution to this [policy-making] process. Their rights in this arena are therefore limited, but their responsibilities for self-education and self-surveillance remain" (Kerr 2003b, 221).

This division between citizens and experts can be seen for example in the structures of UK Biobank, in which the role of the citizen was set up as "one of self-surveillance and information provision to clinicians rather than as members of any independent overseeing body" (Ibid., 218; see also discussion in Dickenson 2013, 187). In contrast, some other governments *consult* citizens, for example for Denmark's biobank or in EU policy making, where patients "help [...] formulate research and ethics policy" (Heath, Rapp, and Taussig 2004, 165; see also discussion at the beginning of this chapter). At best, the involvement of patients/ citizens stretches towards this consultative role, while their general responsibilities have increased, including self-surveillance, involvement in research activities, and the donation of information and samples. The divide between the role of the citizen and the realm of science and the bioeconomy is maintained by institutionalised specialist knowledge, in spite of patients' increased expertise of their own conditions.

Rose and Miller point to the constitutive role of expertise in "advanced liberalism", where they enable the economy of governing as little as necessary by maintaining the public/private divide (N. Rose 1993; Miller and Rose 2008). In this,

experts fulfill a double function: on the one hand “[experts] would ally themselves with political authorities [...] translating political concerns [...] into the vocabulary of management, accounting, medicine [...]”, while also “[o]n the other hand, they would seek to form alliances with individuals themselves, translating their daily worries [...] into a language claiming the power of truth, and offering to teach them the techniques by which they might manage better [...]” (N. Rose and Miller 2010, 206). The discussion in the previous section on the subversive potential of biopolitical challenges showed that this use of the language of truth can contain the potential for challenge to the political discourse, but it also instils “self-regulatory techniques [...] in citizens that will align their personal choices with the ends of government” (Ibid.).

As the previous chapter argued, IP normalises specialist knowledge and elevates a particular vision of life over other, more complex versions. In addition to this, the area of IP law needs to be understood as a very specialist area of knowledge itself, which has high entry barriers contained in specialist legal knowledge of IP procedures and in high costs for registration and enforcement of rights. These requirements make it necessary for IP holders to be highly organised and to have sufficient funds for the maintenance of their rights. Specialist lawyers are often required for the actual registration procedure of IPRs – which, in a similar way to medical experts, translate the applications of individuals “into a language claiming the power of truth” and also work with authorities overseeing the area of IP policy, translating policy preferences into the language of IP management. These structures align choices over directions of research with the ends of the IP system – through “self-regulatory techniques” incited by patentability criteria. These criteria ensure the economic utility of research outcomes and enable IP to “govern at a distance”.

The specialist area of IPRs thus can be understood as fulfilling the function of experts in the governing of the problematization of life, translating concerns and inciting appropriate behaviour of subjects. In this, IPRs are also instrumental in maintaining the division between the public area of direct government intervention, and the private area in which the priorities of governmentality “govern at a distance”. Criteria for economic utility of research conduct the conduct of IP holders. But importantly, the high hurdles for participation in the IP regime towards all other subjects need to be understood as part IP’s governing of life as well. Examples of challenges by active “biological citizens” show that they are either given the option of using IP themselves (as in the case of PXE), or of participating in a research project

by signing a blanket consent form transferring all rights – and thus being entirely excluded from IP. In this way, IP continues to structure the participation of “active” patients in decisions on the further use of information derived from their donation, especially for economic purposes – thus shielding this area from challenges posed by active citizens who may seek to use genetic information for other purposes. This is where the tactical dimension of IP’s role becomes apparent, which maintains the operation of economic circuits of exchange while challenges based on genetic conceptions of life are being kept at bay.

The increasing relevance of genetic knowledge as part of the genetic disposition also intensifies the tactical dimension of this division. IP’s role establishing control over research agendas and economic use of donations needs to be interrogated as a separate power exercise to that of the “commodification” of life. The increasingly tactical use of IPRs as a regime for exclusion from this particular domain is especially obvious in biobanks, where rhetoric emphasises altruistic contributions. Here, IPRs undoubtedly continue to separate the use of donations by the biobank from the sphere of influence of the “biological citizen”. The emergence of new justifications for this exclusion is especially telling, showing that IP is engaging with new demands by patients. Kerr points out how this division is presented as being in the public interest: “In these discussions, the public’s interests (to better drugs and diagnostic tests) are to be secured through the entitlements of the private sector to own genetic knowledge and the public’s obligation to facilitate this by co-operating with research” (Kerr 2003a, 48).

The more frequent reference to research as being in the interest of public health shows that IP is responding to new priorities that otherwise would challenge its legitimacy – but this response also has subversive potential. While IP’s intervention continues to ensure the exclusion of direct interferences by “active” citizens in research agendas and in the economic use of samples, it also opens a debate about IP’s relation to life and health that had previously been deemed “settled” (Rajan 2006, 64) by bioethical arrangements outside of IP. This leads to a contestation of IP’s legitimation within a new frame of reference, which is explored in the next sections and the next chapter. Debates about the role of ‘research patients’ show how IP negotiates the demands of patients as a regime for exclusion, encouraging contributions to research but not granting broader rights of participation implied by

notions of ‘citizenship’. This is then contrasted with new approaches to IP in citizen’s science projects, which depend even more on the motivation to contribute to research.

3.2. *Exclusion in the name of research: IP and the notion of the ‘research patient’*

IP’s exclusion of patients from control over their donated materials and information can thus be read as governmental ‘management’ of biopolitical challenges. This exclusion can for example be traced in the UK government’s recent life science policy, announcing an “opening up [of] the NHS” and giving all “willing patient[s]” the chance to be “a *research patient*”, as “[i]t is simply a waste to have a health system like the NHS and not to do this kind of thing” (Number 10 2011, emphasis added). As part of this strategy, the UK government seeks to “consult on actually changing the NHS constitution so that the default setting is for patients’ data to be used for research unless of course they want to opt out”⁶⁹, so that “every time you use the NHS you’re playing a part in the fight against disease at home and around the world” (Ibid.). Notably this was not a concession granting patients the potential empowerment of being research *citizens*, but rather a statement marketed as a “game-changer” to the pharmaceutical industry, addressing the then imminent ‘patent cliff’ and the recent closures of Pfizer’s laboratories in Sandwich and AstraZeneca’s at Charnwood (Ibid.).⁷⁰

This strategy is part of wider changes in the UK life science sector aiming to make genetic information available for research. These consist for example of the recent completion of UK Biobank, and the widening of the UK’s Life Sciences Strategy to include the sequencing of whole genomes of cancer patients. The ‘100,000 Genomes Project’ aims to make the “UK [...] the first country in the world to introduce the technology within a mainstream health system, with up to 100,000 patients over three to five years having their whole genome – their personal DNA code – sequenced” (Number 10 2012; Genomics England 2015). The “unlocking [of] the power of DNA data” is meant to “revolutionise [the] fight against cancer and help

⁶⁹ This proposed change is highly reminiscent of Iceland’s controversial (overturned) biobank legislation (see also Weldon 2004, 165). The UK government’s policy initiative has since given rise to the (failed) consultation on the *care.data* initiative, seeking to combine medical records with date of birth, full postcode, NHS number, and gender of each NHS patient in a commercial databank (NHS Choices 2014).

⁷⁰ This statement was made for the benefit of the Financial Times’ Global Pharmaceutical and Biotechnology Conference. The ‘patent cliff’ refers to the simultaneous expiration of a large number of important pharmaceutical patents at this point in time, without an equally strong range of follow-up products in the development pipeline (Y. Chen, Varghese, and Prescott 2012).

100,000 NHS patients” (Number 10 2012). Overall this strategy seeks to open genetic sequences and the NHS health records to research projects and exploit this data in economic circuits of exchange, without granting citizens a say in this use beyond the basic level of their (presumed) consent. The failed ‘*care.data*’ programme sought to open NHS records to “carefully chosen”⁷¹ commercial partners (NHS Choices 2014). Similarly partners would pay licensing fees for the use of information contained in UK Biobank. Patients do not have any direct say in the use of the data derived from their samples, while they are incited to contribute by promises of “help”⁷² and the notion of making an important contribution to the fight against cancer (UK Biobank 2010; 2011). These initiatives thus clearly invokes hope and responsibilities in order to capitalise on donated materials and medical information, while IP imposes a clear dividing line between patients and control over samples in the biobank.

These projects show how new norms of patient behaviour are being created, encouraging voluntary donations for the public good of ‘research’. A new somatic responsibility in the “fight” against cancer permeates contemporary life science discourse more broadly, shown for example in the central message of the 2013 advertising campaign by Cancer Research UK: “By sharing the stories of seven cancer survivors, we can demonstrate that our research is saving lives”, and the tagline “I am alive because of research” below the pictures of individual “survivors” (Cancer Research UK 2013). This change in what it means to be a ‘responsible’ patient can be compared to the situation with regards to organ transplantation, where Wehling “observe[s] a remarkable shift in bioethical discourse away from individual rights and choices towards emphasizing the individuals’ moral duties to collective goods and interests as well as various proposals for new institutional arrangements (among them regulated markets) aiming at an increase in organs for transplantation” (Wehling 2011, 236).

The notion of a ‘research patient’ thus marks a shift of emphasis from participatory rights of citizens towards a duty of patients to contribute to a collective good by volunteering information and samples.⁷³ IP then implements the exclusion of

⁷¹ There is no indication of the criteria that may apply to this choice (NHS Choices 2014, see question on “Will confidential information be shared?”).

⁷² This very vague notion of ‘help’ derived directly from the donation undermines assumptions of informed consent, as Weldon argues (2004, 166). She also questions the focus on individuals, at the expense of collective forms of identification such as society, families and citizenry (Ibid., 162).

⁷³ The personal genomics firm *23andMe* encourages the continued participation of donors by giving them titles such as “research pioneers”, “research trailblazers”, and “research captains” – or even

the “active” and responsible patient from any involvement in the use of these samples. This very effectively limits potential challenges made by “biological citizens”, thus ensuring control over samples for research and the bioeconomy. This shows how IP exerts power, but also raises the question for how much longer this wholesale transfer of control is tenable. The emerging area of *citizens’ science* already explores greater participatory rights of the individual donor.

3.3. *Citizens’ Science*⁷⁴ – Contesting IP’s exclusionary regime?

Other recent biotech projects explored a different form of involvement of the individual in research: crowd-sourcing funds and samples, and addressing the individual as a citizen, not a patient/donor. One project sought to decipher the microbiome⁷⁵, and promised to be the “World’s FIRST citizen science project to sequence the human microbiome.” In contrast with other biobanks, they state: “**We will involve the public** in not just collecting the samples, but in analyzing the data, generating and testing hypotheses, and doing as much official ‘science’ as possible. We want this to be the first shot in a revolution in how science is done around the world” (uBiome 2013, emphasis in original). In this crowd-funded project, individual participants pledge money to contribute, and receive a test kit (and a t-shirt) in return for their investment.

The approach to IP on the information contained in this biobank is also different: “**Your data is open to the world...** if you choose. Your data is yours – you can download it, share it, do whatever you want with it. We encourage you to opt-in to share your data with our scientists, but we respect your privacy and will not force you to do so” (Ibid., emphasis in original) – this seems to represent a different way of establishing a biobank, but also raises concerns with regards to the consent structure in place. Research conducted on genetic material aims to explore its potentialities,

“active genomes” (Dickenson 2013, 186). These pioneers have no share in the IP derived from their donations. 23andMe’s first patent however took some of these pioneers by surprise, and caused outrage (Ibid., 191).

⁷⁴ Citizens’ Science refers to projects which seeks to involve laypeople in genuine research, for instance in evaluating images from satellites, observing nature, or in games “creating [a] large-scale library of synthetic RNA designs” (Eterna 2015; overview see Scientific American 2015).

⁷⁵ The MicroBiome represents the genome of the bacteria living on and in the human body, and differs depending on the part of the body. Research looking at the influence of bacteria on health is a relatively recent interest, but can also be seen as part of the ‘post-genomic’ turn of the life-sciences. uBiome states “The microbiome may be as important to human health as the human genome, but unlike the genome, you can change your microbiome. Because of this amazing potential, understanding the microbiome has become one of the most important scientific inquiries of our time” (uBiome 2013; see also Arthur 2013; Harman and Wakeford 2014 on the microbiome and birth).

thus complicating statements about its likely future content – which creates problems for possibilities of a later withdrawal of consent, and the continuing further usage and treatment of the information derived from it. If “your data is yours”, this also raises questions about the later publication of research findings, and about the potential raising of license fees for third party usage. However, in a project that relies entirely on donated funding and voluntary provision of samples, the likely participant will already have a strong desire to voluntarily contribute to research, which may serve to keep potential issues at bay.

This strong desire to contribute to research, and the fact that in this particular case it was strong enough to raise over three times the originally required amount of money, shows how much the responsibility to optimise health has become a powerful motivator for voluntary contributions to genetic research.⁷⁶ In the example of the microbiome project, individual contributions go far beyond the involvement needed for traditional biobanks. But in contrast to these well-developed responsibilities, definitive rights of participation connected to the notion of citizenship are not as pronounced – even in the microbiome project, which is far more open than other projects.

The rhetoric of citizens’ science presents knowledge and research as a form of general empowerment, which enables individuals to understand the ‘truth’ about their bodies. Its relation to IP is still largely untested, as projects are still relatively new. While these participatory structures can challenge IP’s exclusionary function, the empowered citizens in these projects fail to challenge the new responsibilities of the subject. Instead, as the identity of the genetic citizen is based on knowledge of their genetic condition, this ‘empowerment’ of the subject automatically reinforces the validity of genetic truth discourses, and the responsibilities arising from them.

Healthcare practitioners and national health services also tap into this notion of empowerment without actual rights by promoting *personalised medicine* (for instance based on pharmacogenetics⁷⁷). This vision of personalised medicine hopes for example that “in the future, we will all carry SMART cards, which will contain our genetic information. Using these SMART cards, a GP will be able to prescribe the

⁷⁶ Another example is the “open source” genome of Manu Sporny (Sporny 2011; Sporny 2015). This shows a strong interest in being part of research but also becoming part of the bioeconomy, being quite literally an ‘entrepreneur of the self’.

⁷⁷ Pharmacogenetics is “the study of the genetic basis for the difference between individuals in response to drugs” (Institute of Translational Medicine 2015a).

right drug at the right dose at the right time” (Institute of Translational Medicine 2015b). This is also part of the UK’s new life sciences strategy, harnessing “three quite fundamental shifts in the practice of modern medicine: a coming revolution in biomedicine, in data for quality and proactive care, [and] in the role that patients play in controlling their own health and care” (D. Campbell 2014). Importantly, a national programme of “personalised medicine” would formally impose new obligations on the individual patient to know *and* to disclose their own genome. This form of inclusion, however, would still fall short of the participatory rights implied by the notion of citizenship – especially when faced with exclusion from control over information by means of blanket transfer of IP. IP’s affinity with this notion of limited empowerment thus ‘manages’ biopolitical challenges by active genetic patients, deflecting demands for participation in the further usage of information.

Citizens’ science challenges the exclusion of patients from control over expert knowledge by IPRs to some extent, yet simultaneously reinforces somatic responsibilities of the self-actualising subject. The emergence of notions of the ‘research patient’ stressing subject’s empowerment through contributions to research can be read as evidence of processes of accommodation folding the active patient’s demands into the existing system without disruption. By excluding participation by anyone but the IP holder, the IP system plays a central role in ensuring control over the bioeconomy’s further use of information derived from donations and national medical health records. This exclusionary function of IPRs has thus far managed challenges from a “biopolitics from below” (Raman and Tutton 2010, 722, see above), which however in the long run could fundamentally question the economic utility of IPRs as a whole. The analysis highlighted how new forms of IP strategies put pressure on the economic and biopolitical legitimacy of this exclusionary regime. Alternative IP strategies are also emerging in the sector of global health, reflecting a growing influence of patients’ concerns. The last section points out how juridical subjects such as medical research charities and public-private-partnerships (PPPs) are challenging IP in a “biopolitics from above”, strategically employing IP with the aim of improving the life and health of populations.

4. Contesting exclusion in a “biopolitics from above” – New strategic uses of IP

So far this chapter set out various ways in which the exclusionary effects of IPRs are being challenged by a greater emphasis on patients’ concerns – either voiced directly

by patients, or taken on board by new juridical entities such as medical research charities. These began using IP in novel ways, not for economic gain but as strategies for the improvement of patients' health. This section argues that on the international level, legal subjects such as public-private-partnerships, patent pools, and medical research charities are similarly operating in an emerging somatic ethics within international organisations located at the intersection of health and the economy. Due to its strong links to institutions, this ethics is more reminiscent of what Raman and Tutton term an "old biopolitics from above" (Raman and Tutton, *Ibid.*), implementing strategies that take into account concerns for the life and health of populations worldwide. It is argued that these entities' tactical use of IP is further evidence of IP's emerging role as a tactics of governing challenges posed by a politics of life. Specific strategies engaging with exclusion within these organisations are analysed in the next chapter in greater detail. This section introduces a range of new juridical subjects that operate at the international intersection of health and IPRs, challenging the exclusionary effects of IPRs – but still operating within this system instead of radically altering it. The next chapter then explores more radical challenges to the international IP regime, in what has been interpreted by Lezaun & Montgomery as "a new moral economy of R&D" (2015, 5).

4.1. IP strategies of Medical Research Charities – Charity or business venture?

As already set out above, Medical Research Charities (MRCs) such as the Cystic Fibrosis Foundation are increasingly actively making use of IP for the attainment of their goals. An example of this can be found in the declared mission of the Wellcome Trust, one of the biggest MRC in the UK: "The mission of the Wellcome Trust is to foster and promote research with the aim of improving human and animal health. This is the driving force behind all of the Trust's charitable funding activities, and the basis for its policy on the protection and use of intellectual property rights" (Wellcome Trust 2000). This marks a turn away from charities' previous relative neglect of 'commercial' interests such as IP. Looking at different instances of patenting, the Wellcome Trust sets out its strategy in more detail, for example with regards to the patenting of DNA sequences: "[...] the Trust is supportive of these if there is sufficient information to indicate that the DNA sequences in question can be used to develop healthcare benefits. The Trust does not support the patenting of raw DNA sequences in the absence of such information. This is in line with EU law [...]" (*Ibid.*). MRCs are

thus not generally opposed to IP and are operating within the same parameters as private industry – even with regards to information derived from human genetic materials.

This is reflected in the advice given by the Association of Medical Research Charities (AMRC) on the use of patents and their potential for the sector:

“Although charities cannot support a piece of research solely for financial gain, there may be circumstances where a charity’s objectives can be best achieved by ensuring that IP is protected and/or exploited. Indeed, because of the major costs involved in drug development and registration, failure to obtain IP may jeopardise its likelihood of successful introduction for patient benefit.” (AMRC 2007, 2)

MRCs thus use IP in the same way as the pharmaceutical industry⁷⁸, but in a manner consistent with priorities such as the promotion of healthcare and the targeting of research according to patients’ needs.

At the same time, the pharmaceutical sector is turning towards the “public good”: “[a] new generation of leaders in the pharmaceutical industry is seeking to solve the dilemma of how to deliver value to their shareholders while meeting expectations that they should promote ‘the public good’” (CEWG 2012a, 29). F. Hoffmann-La Roche Ltd. tries to resolve the tension between profit and public good by pointing out: “1,000,000,000 CHF investment; 7,000,874 hours of work; 6,587 experiments; 423 researchers; 1 drug”, thus highlighting the cost and effort needed for the development of *one* drug (Roche 2012).⁷⁹ The importance of IP for the development of medicines is explained further: “Like all research-based companies, Roche needs patent protection to be able to recoup its long-term investments in

⁷⁸ This policy advice of the AMRC also responds directly to the UK government’s emphasis on creation of IP, “stress[ing] the economic advantages of using scientific knowledge to create wealth” (AMRC 2007, 1).

⁷⁹ F. Hoffmann-La Roche has one of the most elaborate and transparent internet presentations with regards to Corporate Responsibility, Ethics and Patient Involvement (Roche 2015a; 2015b; 2014). Their statements are largely representative of those by other leading international pharmaceutical companies. On 14.5.2012, the website of Merck (US) read “Improving Health Improving Lives” (<http://www.merck.com/about/home.html>), AstraZeneca’s tagline was “Health Connects Us All” (<http://www.astrazeneca.com/Home>), Pfizer outlined its “Commitments for a Healthier World” (Pfizer 2015), and other companies prominently placed their initiatives in the field of access to medicines and treatment of neglected diseases, for example Novartis’ initiative in connecting with World Malaria Day (Novartis 2012).

research into new medical solutions and to pursue further innovations. Without patents and pricing that encourages real progress, innovation is impossible” (Roche 2014). This has become the standard argument for IP in the context of health, highlighting the need for returns on investments that improve health for all – which, importantly, still prioritises economic profit over health. In contrast to that, MRCs prioritise improving life and health, which can, as shown above, give rise to different licensing strategies to that of the pharmaceutical industry.

While MRCs’ IP strategies stay within the economic system, their strategic approach to IP management emphasises control and is more flexible and context-dependent, as for example the case of a one-dose oral typhoid vaccine shows:

“the Trust has funded a company to further develop a proprietary technology for application to a disease area that was not attractive to commercial investors. The Trust has structured the IP management arrangements to encourage the company to exploit Trust-funded research itself, but retains rights to intervene if the IP is not exploited for the benefit of the developing world.” (Wellcome Trust 2006)

But the use of IP also highlights that this remains an adjustment within the existing economic system’s parameters, not the introduction of a radical alternative. Patent pools and PPPs are using similar flexible IP management strategies in the sector of global health, addressing the needs of populations in developing countries in particular.

4.2. Patent Pools and Public Private Partnerships – Prioritising global health?

Within the sector of global health, new patent pools seek to address public health for the benefit of patients in developing countries, who are usually excluded from pharmaceutical companies’ considerations. Patent pools bring together available patents regarding one particular disease, making information about existing patents accessible and negotiating voluntary or reduced licenses on existing medicines, thus making research and distribution of knowledge in the pharmaceutical sector more effective and flexible - especially where it comes to patents covering pharmaceuticals that are needed in developing countries. In general terms, patent pools address the “anticommons effect” of “the existence of multiple patents, held by multiple patent

owners (*a patent thicket*)” (Verbeure 2009, 3, emphasis added) – but they do not contest the existence of IP in general. In contrast with the situation regarding software patents, “[a] principal argument for patenting biomedical inventions is the fact that typically, post-invention development costs far exceed pre-invention research expenditures, and firms are unable to make this substantial investment without protection from competition” (Ibid., 15).

Patent pools seek solutions to the exclusionary effects of IP within existing international economic structures, especially in situations “when the IP rights necessary to arrive at a commercial end product such as a kit for diagnostic testing are held by patentees too numerous or heterogeneous to agree on licensing terms” (Ibid., 15f.). The recently established international *Medicines Patent Pool* is an example of a single-issue international patent pool focusing on HIV/AIDS medication. Their aim is to “[make] patents work for public health, while giving pharmaceutical innovators compensation for their work” (Medicines Patent Pool 2011).⁸⁰ Lobbying on behalf of HIV/AIDS patients in developing countries, this patent pool successfully negotiated a range of voluntary licenses with pharmaceutical companies. This may have been particularly successful due to the international focus on HIV/AIDS (see for example Elbe 2005), increasing the pressure on companies to make their treatments available to patients in developing countries in particular. The combination of this pressure with a relative “failure” of the market in developing countries makes a compelling case for voluntary licences in these cases without a significant loss of profits (see next chapter).

The use of voluntary licenses by patent pools shows that this approach can only work in specific contexts, limited geographically to mainly least-developed countries. The executive director of the Drugs for Neglected Diseases initiative (DNDi) criticises WIPO’s patent pool Re:Search (WIPO 2012b) because of its limited geographical reach: “it currently aims to improve access to neglected disease medicines in just the 49 least-developed countries, [whereas] he thinks it should aim to increase access for all developing countries” (quoted after Frantz 2012). But many

⁸⁰ Another example is WIPO’s Re:Search initiative, which pools IP and information in the area of tropical diseases, tuberculosis, and malaria (established 2011, merged with the Pool for Open Innovation, see WIPO 2012b). Its remit is more comprehensive than that of Medicines Patent Pool, comprising “not just intellectual property (IP) but also intellectual capital, including screening hits, expertise and know-how” (Frantz 2012).

PPPs also use tailored IPRs strategies within geographically limited exemptions granted by the pharmaceutical industry.

PPPs have become significant partners of international organisations in the implementation of framework aims in the field of global health, and have specialised on particular diseases and local contexts in the process (see Rushton and Williams 2011). These targeted projects can be very effective but are more difficult to replicate on a larger scale, as the Medicines Patent Pool had to discover. An idea of the sheer number of emerging PPPs can be gleaned from the *Health Partnerships Database*, which seeks to “systemically [*sic.*] collect data about a new breed of PPPs coalesced around the health needs of the poor” (ESRC Innogen Centre 2008).⁸¹ In the best case, “[t]his relatively new trend in global health cooperation is demonstrating significant possibilities for tackling problems that formerly seemed intractable, particularly those requiring increased research and development (R&D) on drugs and vaccines for diseases disproportionately affecting the poor” (Buse and Waxman 2001, 748).

PPPs and Product Development Partnerships (PDPs) make strategic use of IP by deriving income from the products they developed (Brooke et al. 2007, 1757). The licensing regime employed by PPPs can be flexible and take into account the relative economic positions of the licensees – as in the example of the licensing regime of FIND Diagnostics:

“When research has the potential to result in an invention (patentable or not), we negotiate with the partner(s) in advance to ensure that the IP rights generated by the project will be managed in such a way that the benefits are passed on to patients in resource poor settings. Industry partners assign all rights to FIND for royalty-free use of their technology in the public and private non-profit sectors in high endemic countries, while the industry partner retains distribution rights for developed countries and the private sector in developing countries. This enables the partner to recover R&D costs and to create the returns needed to develop new technologies.” (FIND Diagnostics 2015)

⁸¹ The Health Partnerships Database was previously called the Initiative on Public-Private Partnerships for Health (IPPPH), which closed down in 2005.

Just as in the case of patent pools, this strategy counteracts IP's exclusionary function in a particular geographical and social context. This limitation is intentional, as a group of PDPs points out in a position paper for the EU's Horizon 2020 Framework: "PDPs were created specifically to address the research gap present in the development of products for diseases that lack viable commercial markets. PDPs use different models of IP management and licensing arrangements in their partnerships with academic institutions and private companies, aiming to de-link the costs of R&D from the cost of final products" (AERAS et al. 2012).

Lezaun & Montgomery note that PPPs have begun to share IP, and use it "as a lever to attract others into risky collaborative ventures" (Lezaun and Montgomery 2015, 3; see also Williams 2012). This is contrary to the usual exclusionary function of IP, and gives rise to "a new moral economy of R&D" emphasising collaborations (Lezaun and Montgomery 2015, 5). However, PPPs combine priorities set by public sector organisations such as the WHO with the mechanisms of the private sector. This approach contains both the potential for more targeted and efficient implementation efforts and the unpredictable consequences of introducing the private sector's economic rationale to the area of 'public' health. This has given rise to fears "that new partnerships are leading down a slippery slope towards the partial privatization and commercialization of the UN system" and "that partnership enables nation states to abdicate their responsibilities for the promotion and protection of their citizens' health", as for example "it is charged that the independent setting of standards was jeopardized during the elaboration of the guidelines for the management of hypertension because of the influence of a firm that stood to benefit from them" (Buse and Waxman 2001, 750). Despite these concerns, PPPs are increasingly involved in global health policies, and the WHO sees PPPs and PDPs as central to the future financing and facilitation of research and development of medicines (CEWG 2012a, 31).

Thus neither patent pools nor PPPs/ PDPs are intending to challenge the notion of IP in general. They rather address the needs of certain patients from within the parameters of the international economic system. In this way they acknowledge the increasing demands of patients while they are at the same time reinforcing the general function of IP – from which they derive income. However, the emerging "moral economy" surrounding the financing of R&D in global health projects combines the use of IP with a politics of health, in which PPPs can be seen to be

“governed at a distance” as they implement centrally defined priorities in small-scale private projects. Instead of focusing on IP’s economic function, it is argued in this thesis that PPPs are becoming involved in a version of somatic ethics developing within international organisations operating at the intersection of global health and the economy. The result is an ongoing process of accommodation between biopolitical and economic priorities, on the national and international level. The next chapter explores particular challenges to the IP system arising from this ethics, which even include frank debates on the introduction of alternatives to IP. Examples of human rights challenges and an increasing focus on the argument of ‘market failure’ could have radically unsettling effects on IP’s legitimation.

Conclusion

This chapter set out challenges to the IP system made by “active” patients defining their identity and wellbeing increasingly on the molecular level. This showed how the subject’s identity is affected by a change of the truth over life, and how the subject’s attention to health on the genetic level can present an increasing challenge to IP’s exclusive control over knowledge. Patients’ participation in decisions on the further usage of knowledge can lead to new strategic uses of IP, as the examples of PXE International and MRCs showed. Even on the international level, a range of juridical subjects uses IP in strategic ways to address the needs of patients especially in developing countries. However, most of these strategies remain regional exemptions to the IP regime, and do not challenge the overall legitimacy of this system. IP’s exclusionary structures still prevent the participation of active patients in decisions on the further usage of genetic information. At the same time, demands for participation made by active patients further entrench healthcare responsibilities of the “genetic” citizen, who is encouraged to donate materials and information to research. IP can thus be understood to “govern at a distance” in the same manner as experts, ensuring the complete transfer of control over genetic knowledge. In contrast to this management of active patients, the next chapter evaluates IP’s response to the use of human rights and the ‘market failure’ argument in strategies that pose a more fundamental challenge to the IP system.

Chapter VI Contesting exclusion on the international level – Emerging strategies in the name of life

“The game is in Europe, but the stake is the world.” (Foucault 2008, 56)

The function of IP as a regime for exclusion appears in its starkest form on the international level. Here, as this chapter sets out, the complete division between IP on human genetic sequences and the ‘source’ of this material is even more entrenched. Tellingly, debates about IP’s treatment of genetic materials are being mostly held in international organisations outside of the IP system, such as the Convention on Biological Diversity (CBD) and the supplementary *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity* (‘Nagoya Protocol’). However, since the *Doha Declaration on TRIPS and Public Health* (2001) even the core of the IP system has begun to engage with questions of life and health, and the previous chapter set out how legal subjects such as patent pools and PPPs have employed IP in new strategies implementing global health aims. Some analyses go as far as saying that a “paradigm shift” towards greater openness is underway in the IP regime (Morin 2014; Lezaun and Montgomery 2015; to some extent also Williams 2012; Pogge, Rimmer, and Rubenstein 2010; Gibson 2009). This chapter analyses the emergence of particular challenges to the IP system’s relation to life in policy debates in WTO, WHO, and WIPO. It argues that in these debates, the IP regime is beginning to respond to tensions that could more fundamentally disrupt its legitimacy.

This chapter focuses on detailed processes of transformation in the role of IP within major international organisations, which differ from the individual challenges brought by active patients and medical research charities explored in the previous chapter. The connection between the international IP regime and global health stretches across several international organisations, which usually operate entirely autonomously from each other. Against this backdrop, the emergence of a trilateral cooperation between WIPO, WHO, and WTO (2013) and a developmental agenda within the IP organisation WIPO are striking and challenging changes. Focusing on IP

as a regime of global biopower could provide a critique of the exclusionary character of this regime as a foundational exclusion or “abandonment” of large parts of the world’s population (Selmeczi 2009; Agamben 1998; Godoy 2013, see discussion in chapter III). This perspective can however not explain the emergence of new IP strategies and a “new moral economy of R&D” (Lezaun and Montgomery 2015, 5) within global health projects. This chapter goes beyond this critique, and directs attention to emerging strategies that challenge IP’s relation to life in the international sphere, where slow change is brought about even at the heart of the IP system. In a newly developing policy area of IP and global health, arguments relying on the right to health and strategies converging around the concept of ‘market failure’ are increasingly contesting IP’s legitimacy.

1. IP as a regime for exclusion on the international level

The places of origin of human genetic materials and the location of industries involved in deriving further use from these samples are distributed very unevenly across the globe. Because of this, the use of IP on human genetic sequences has in the past given rise to widespread controversy internationally. Critiques have termed these practices “biopiracy” and argued that they amounted to a second “enclosure of the commons” (Shiva 1998; Boyle 2003; May 2010, see discussion in chapter II). In response to these critiques, new mechanisms for access and benefit sharing (ABS) were suggested and developed especially with regards to plant genetic material. The Nagoya Protocol to the CBD is the most tangible result of this process, and came into force only very recently (12th October 2014). However, important members of the international community such as the US and Japan are still not signatories to this instrument or have failed to ratify, and the practical implementation of measures still remains largely unexplored (see overview in Oberthür and Rosendal 2014). Furthermore, the relation between this ABS agreement and TRIPS remains unclear, as the Nagoya Protocol and the Convention on Biological Diversity (CBD) have been negotiated outside of WTO structures.

Processes of exclusion need to be understood as a separate strategic power exercise of the IP system, as shown in the previous chapter. This chapter argues that the IP system exercises power not only by bestowing exclusive rights on the IP holder, but also by operating in relative isolation on the international level. The continuing international division between IP on information derived from human

genetic materials and the places of source of this material highlights IP's exclusionary role in its starkest terms. On the basis of this realisation, the chapter then explores strategies challenging IP's institutional isolation on the international level within an emerging frame of reference centred on life, which requires new legitimations from the previously entirely separate IP system. These responses are better understood as instances of governing. This thesis' analytical perspective on IP as an emerging tactics of governing highlights how IP's exclusivity is beginning to be contested in debates about IP and health, and IP and human rights, held within pro-IP international organisations such as the WTO and WIPO. The IP system continues to fulfil its economic role, however, this now needs to accommodate demands made on the basis of life and health, leading to a process of accommodation in which IP begins to act as a tactics of governing between life and the market.

1.1. Deriving exclusive rights from international bioprospecting and biobanking projects

The relation between IP and genetic conceptions of life on the international level has been marked by several highly controversial instances of “bioprospecting” (Robinson 2010, 11) in developing countries followed by registration of gene patents on the gathered ‘materials’ in industrialised countries. Most notable amongst these was the Human Genome Diversity Project (HGDP)⁸², which collected a diverse range of genetic samples from different distinct peoples across the world, and gave rise to allegations of racism and ‘biocolonialism’. Indigenous peoples referred to it as the “Vampire Project” and strongly criticised the range of chosen donor populations and the patents derived from the samples later on (see Thacker 2005a, 134). An unrelated patent application on a leukaemia-resistant human T-cell line derived from a Papua New Guinean, filed by the US Department of Health and Human Services and the National Institutes of Health in 1993 (Oriola 2007, 6; Thacker 2005a, 134) was also heavily criticised for the cursory way in which it dealt with the original donor. These issues were addressed in the later Human Genome Project (HGP) in a dedicated ‘ELSI’ (Ethical, Legal and Social Implications) programme, entirely funded as part of the larger project itself. This programme focused in particular on the question of

⁸² This is a separate human genome project to the Human Genome Project (HGP), which focused on the mapping of all human genes, sequencing multiple variations of each gene in order to come up with a more complete picture.

informed consent. IP is usually not included in such formal considerations of bioethics beyond the question of informed consent.

The HGP proved less controversial due to the ELSI programme and the project's less racially charged connotations, however, further controversies arose when an Australian pharmaceutical company named Autogen attempted to create a biobank containing blood samples and DNA of Tonga's people in 2000 – also seeking to capitalise on this community's relative isolation and distinctiveness. The project was dropped in the face of vociferous criticism from Tonga's population, which complained that the informed consent procedures disregarded Tonga's particular social structure and the importance of the family unit within it. Consent could thus not be obtained from the individual alone, but needed to take into account the views from the extended family group (Nwabueze 2007, 167). However, Autogen's project addressed previous criticisms made of 'bioprospecting' programmes by promising to share the proceeds of any commercial products derived from the research, establishing laboratories on Tonga and assigning property rights over individual genetic samples to Tonga's government – effectively nationalising this property (Ibid.).

A similar approach to property was taken by deCode's Icelandic Population Biobank. However, in the Icelandic case "informed consent was claimed on behalf of the people of Iceland through an act of parliament" (Senituli and Boyes 2002, 4; see also Fortun 2008). This model differs from other biobanks, which adopted a much more protectionist position towards the material and background information, as for example was the case in Sweden (Nilsson and Rose 1999, 894). Part of the Icelandic plan was to establish a Health Sector Database (HSD) in the *Act on a Health Sector Database (No. 139/1998)*, passed by the Icelandic parliament on 17.12.1998, "which would link its clinical and research data to both the Icelandic health care system records and the genealogies" (H. Rose 2003, 78).⁸³ The Icelandic government created a tissue bank "to complement the HSD" in the *Act on Biobanks No. 110/2000* (Nwabueze 2007, 156). This tissue bank and the HSD operated on the basis of licenses, so that the property in the materials collected remained with the government

⁸³ Iceland was selected because of its moderate size, geographical isolation, good level of healthcare and high per capita income. Furthermore the Icelandic population was also judged to display a particular "enthusiasm for science and technology and its fruits [that] is not shared by most other Europeans", and to be a "'good' population because of their claimed homogeneity" (H. Rose 2003, 80 and 81).

of Iceland. However, the blanket presumption of consent encountered strong criticism, and “six years later that statute was overturned as unconstitutional, and subsequent national biobanks such as those in Australia, Estonia and the United Kingdom have required explicit consent at the time of donation” (Dickenson 2007, 126).

Interestingly, the transfer of IP was not directly discussed in ethical debates, even in these very contentious examples of biobanks and bioprospecting projects. Bioethics debates usually revolve around the issue of informed consent to counter allegations of ‘biocolonialism’ perpetrated by companies based in industrial countries, and are slowly also including problems of IP in informed consent structure (Dickenson 2004). The assumption of IP rights by the Icelandic government did not give rise to a debate similar to that of its presumed consent – and still does not, as the details of the transfer of rights in the recently established structures of UK Biobank show. Where it comes to intellectual property, the consent form of UK Biobank clearly states: “I [...] relinquish all rights to these samples which I am donating to UK Biobank” (UK Biobank 2011). There is an option for withdrawal from the programme promising “UK Biobank would destroy your samples (although it may not be possible to trace all distributed sample remnants)” (UK Biobank 2010). Thus the transfer of property rights is permanent, even though the samples themselves may be destroyed at a later date. UK Biobank then grants licenses to private corporations and scientists for the use of the genetic information (UK Biobank 2007, 13).

Exclusive rights are derived from individually donated samples in all these examples of bioprospecting and biobanking projects – held either directly by a private company or in some cases by the respective national government. These rights are not directly contested in bioethics debates – but they are nonetheless criticised strongly by the Biopiracy and New Enclosure literature. In response, demands for *Access and Benefit Sharing* (ABS) aim to ensure a more direct connection between the donation of the materials and the eventual profits made from the intellectual property and commercialised products derived from this donation – albeit only in the area of plant genetic material. ABS agreements such as the Nagoya Protocol have been debated extensively for example under the CBD, suggesting amongst others a requirement for the disclosure of the provenance of the sample used for a particular patent application – but have not been included into the list of minimum provisions for patentability under TRIPS.

The IP system thus remains doubly exclusionary – assigning exclusive monopoly rights to private entities and at the same time excluding any reference to the origin of samples used for the genetic ‘invention’ in question. This detachedness is mirrored in the division of debates between pro-IP international organisations such as WTO and WIPO, and pro-ABS organisations such as the CBD. This separation between sites of debate also masks a division of interests between industrial, IP-producing countries and developing countries, which are often the location of provenance of samples used in the production of IP. As the next section will show, this division of debates perpetuates the exclusive status of IP, as ABS agreements fail to make inroads on the TRIPS system. While the relation between the Nagoya Protocol and TRIPS is still under discussion, the exclusivity of the IP system remains especially effective in the area of IPRs on information derived from human genetic materials, where no similar ABS agreement has been negotiated.

1.2. Addressing international imbalances through Access and Benefit Sharing

The Nagoya Protocol’s attempt to counteract the exclusionary function of the IP system through a mandatory disclosure requirement must be considered briefly, despite its primary applicability to plant genetic materials and traditional knowledge. It aims to address the imbalance between the cost of maintaining biodiversity and the relative ease in which plant genetic resources can be accessed in bioprospecting programmes, and then commercially exploited by corporations without maintaining any connection to the material’s place of origin. The protocol’s goal of “[creating] incentives for biodiversity conservation” is thus especially addressing the global geographical distribution of resources and industry in this case: “[...] many tropical developing countries are particularly rich in terrestrial species and related genetic resources (GR) and associated traditional knowledge, whereas the technological capacity to exploit GR is concentrated in developed countries” (Oberthür and Rosendal 2014, 1).⁸⁴ A similar geographical division between donors and industry also gave rise to condemnations of the HDGP and other programmes seeking to exploit human genetic materials with particularly ‘interesting’ traits.

⁸⁴ Oberthür and Rosendal point out that “[a]t the onset of the CBD negotiations, developing countries held only about 1 per cent of all patents in biotechnology, and by 2005, that figure had increased to 4 per cent” (2014, 4).

The most ambitious part of the negotiations leading up to the Nagoya Protocol sought to introduce a mandatory disclosure requirement into IP law, containing “the origin of genetic material as well as information to confirm that it has been acquired in accordance with [prior informed consent] and [mutually agreed terms] requirements” (Ibid., 7). This requirement would have established a direct link between patents and the origin of genetic material from which information has been derived – and could thus for example have fundamentally altered the minimum requirements for patentability of information derived from genetic materials. This undertaking proved too ambitious, and was in the end not included in the final text of the Nagoya Protocol.

The introduction of a disclosure requirement is however still under consideration in the ongoing negotiations in WIPO’s Intergovernmental Committee (IGC) on *Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*. WIPO’s IGC is part of the organisation’s larger development agenda, in which this traditionally pro-IP institution is currently engaging. WIPO used to be the central international organisation for IP related matters, until the TRIPS agreement took over this role within the WTO in an instance of strategic “regime-shifting” by industrial countries (Helfer 2004, 18 ff.). While, as an independently funded UN agency, WIPO continues to derive its funding from IP registration fees, and thus remains central to and supportive of the IP system, it has recently begun hosting an ambitious development agenda – arguably more in line with UN human rights standards (on this “resurgence” of WIPO see May 2006, 74; Muzaka 2013).

Since 2001, negotiations in WIPO’s IGC have been navigating a similar split between developing countries and developed countries as the one reflected in the ratification procedure of the Nagoya Protocol – where the EU remained the most important full member representing the interests of developed and IP-producing countries (on the role of the EU in the negotiations and its interests see Oberthür and Rabitz 2014). WIPO in contrast has a much broader range of member states, including the US, which makes these negotiations potentially more likely to bring about change – and thus can be interpreted as a strategic “regime-shift” by developing countries with the aim of “[integrating] rules generated in other international regimes into the organization [WIPO]” (Helfer 2004, 69; also Muzaka 2013). However, industrial countries and the biotech lobby have thus far strongly opposed the introduction of a

disclosure requirement in WIPO's IGC, and continuing negotiations are not getting any closer to resolving this issue (Third World Network 2014; Saez 2014c).

This failure to include a mandatory disclosure requirement both in the Nagoya Protocol and thus far also in WIPO's negotiations highlights the resilience of the IP system's exclusionary function internationally. Oberthür & Rosendal underline this continuing exclusion by pointing out "IPRs are guaranteed by governments and not touched under ABS, while ABS is trying to correct the consequences by delegating to decentralized negotiations between private/public actors" (Oberthür and Rosendal 2014, 8). Thus the Nagoya Protocol's attempt at addressing the division between the source of genetic materials and its commercial exploitation resulted in a treaty that operates outside of IP law – especially as long as the relation between TRIPS, the CBD, and the Protocol remains undetermined.⁸⁵

While the interests of IP-producing countries have thus been enshrined in a very enforceable international legal system, the interests of developing countries remain sidelined, excluded from recognition in the requirements for patentability, and have only limited success within negotiations on international agreements seeking to address this situation. Despite this, debates about IP's relation to life especially in developing countries are being conducted within the most significant international pro-IP institutions. This chapter argues that negotiations about the treatment of genetic resources and the health of populations constitute sites of challenge to the exclusionary function of IP, arising from life as a new frame of reference for IP's legitimation. These challenges and their potential can be better understood as strategies for intervention on the IP system in the name of life and health, in response to which IP begins to act as a tactics of government. Instead of focusing on a possible interpretation of IP as a form of biopower, which as part of the liberal system inscribes a constitutive exclusion of the expendable parts of the world's population, this thesis' reading analyses the detailed processes through which governmental rationalities evolve, and how law becomes a tool of governing in a response to changing conceptions of life.

⁸⁵ The relation between TRIPS and the CBD is still being discussed as part of the review procedure of Article 27.3b TRIPS – regarding the patentability of plant and animal inventions. The 2001 Doha Development Agenda broadened the scope of these negotiations to include the resolution of the relation between TRIPS and CBD (WTO 2015a).

2. The Doha Ministerial Declaration on TRIPS and Public Health: Problematizing the health of populations

The exclusionary paradigm of the IP regime is undergoing change. New debates are increasingly emphasising “greater policy flexibility and greater access to knowledge” (Morin 2014, 276; Williams 2012), and the boundary between the public and the private domain is becoming “porous” (Lezaun and Montgomery 2015, 4). The *Doha Ministerial Declaration on TRIPS and Public Health* (2001) constituted the starting point for an ongoing deliberation of the connection between IP and life on the international level, involving the three most significant organisations at this intersection: the World Trade Organisation (WTO), the World Health Organisation (WHO), and the World Intellectual Property Organisation (WIPO). These three organisations have subsequently engaged in explorations of the intersection between IP and life, recently resulting in a trilateral cooperation and the release of a study on ‘*Promoting Access and Medical Innovation: Intersections between Public Health, Intellectual Property and Trade*’ (WHO, WIPO, and WTO 2013). These debates do not directly address human genetic materials, but discussions of IP’s relation to health include all pharmaceuticals and tests currently under development.

It is argued here that these initiatives can be better understood as part of a process of accommodation between IP law and a growing emphasis on the life and health of populations within these international organisations. This emphasis has elsewhere been interpreted as a “new moral economy” in which PPPs are sharing knowledge (Lezaun and Montgomery 2015, 4). This thesis argues that these developments highlight the engagement of these organisations in the wider problematization of IP’s relation to life for the purposes of governing. The Doha Declaration on TRIPS and Public Health established a link between previously entirely separate policy fields and also between separate organisations working on health and IP. This development is beginning to break down the exclusionary regime of IP, giving rise to tensions to which IP law’s reacts responsively as a tactics of governing. The policy debates around IP and life still maintain the exclusionary status of IP, but are increasingly legitimating this with reference to life and health. After setting out the emerging link between health and IP, this chapter turns to challenges formed within these new discourses of legitimation. Here, the confrontation with the right to health and the argument of market failure could present radical challenges to IP’s legitimacy.

2.1. Establishing a link between health and IP: Problematizing global life

The Doha Declaration on TRIPS and Public Health represented a major success on the behalf of developing countries, as Correa points out: “The eventual adoption of a declaration on Public Health and TRIPS was the outcome of a carefully elaborated strategy by developing countries” (Correa 2000, 3). It clearly set out and affirmed the rights of countries to make use of existing flexibilities of the IP system for health purposes, and also contained a moratorium on full implementation of TRIPS for least-developed countries until 2016. In particular, it directly acknowledges “public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics”, and “reaffirm[s] the right [...] to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose” (WTO 2001, No. 1 and 4). These “flexibilities“ are made up of, most importantly, a recommendation of interpreting existing provisions “in the light of the object and purpose of the Agreement as expressed“, also the “right to grant compulsory licenses”⁸⁶, the “right to determine what constitutes a national emergency [...] it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency“, and the recognition that each Member State is “free to establish its own regime for [the exhaustion of intellectual property rights]⁸⁷” (Ibid., No. 5).

Thus the Doha Declaration “[i]mplicitly [...] recognised the concern of developing countries about the effects of TRIPS on access to medicines” (t’ Hoen 2009, 19). As a result, life became problematized for the purposes of governing on a global scale, and the concerns around IP and global health became a new policy area within international organisations. In the wake of the Doha declaration, a much larger number of compulsory licences was issued.⁸⁸ Examples for recent high-profile compulsory licences are those issued by Brazil (2007)⁸⁹ and by India (2012)⁹⁰. India

⁸⁶ A compulsory licence is issued in cases of health emergencies without the consent of the patent owner (WTO 2015).

⁸⁷ The ‘exhaustion’ of IP refers to the limitation of the rights holder’s influence after a licensed sale.

⁸⁸ “By the end of 2007, 52 developing States had issued post-Doha Declaration compulsory licences, indicating that the Declaration has had the desired effect of prompting needy States to make use of the Article 31 exception” (Joseph 2011, 225).

⁸⁹ Between 2001-2007, Brazil mainly relied on the threat of a compulsory licence. In 2007 it finally issued one on AIDS medication (ICTSD 2007).

has since also increasingly developed its own position on patentable subject matter. In 2013 India's Supreme Court denied Novartis a patent on the cancer medicine Glivec (Gleevec), arguing that it did not constitute enough of an innovation compared to its previous version (Supreme Court of India 2013). This announced a stricter approach to patentability as a response to 'evergreening' patent applications, thus expediting the availability of medicines as cheaper generic versions.⁹¹ The production for export under compulsory licence was another contested way in which IP adversely affected developing countries' capacities to improve public health. After debates stalled in 2001, it was finally resolved in 2003 in a further declaration on the implementation of Paragraph 6 of the Doha Declaration (WTO 2003), making it possible to export medicines under a compulsory license to countries that do not have the capacity to produce drugs themselves.

Since Doha, the connection between IP and public health has also been strengthened in the area of *IP management* (CEWG 2012a, 56), in which rules can differ from country to country. This is an area that does not directly address the conditions for the issuing of patents, but looks at the conditions *around* the patenting process, such as regulatory approval for medicines. In this area, bolar provisions⁹², extensions of data exclusivity⁹³ and orphan drug disease rules⁹⁴ are flexibilities that are very regularly considered and evaluated in WTO, WHO and WIPO documents on public health (see for example WTO 2002), and also in a range of other publications and activities in this sector (for example in the business models of PPPs). These flexibilities operate on a level below that of compulsory licenses, which are much more powerful interventions but are not issued very often in practice.⁹⁵

The Doha declaration on TRIPS and Public Health was however not only the result of developing countries' pressure for a stronger recognition of the connection

⁹⁰ This was the first compulsory licence issued by India, raising concerns of a new attitude towards IP in India (Controller of Patents, Mumbai 2012; Estavillo 2012).

⁹¹ 'Evergreening' refers to the practice of extending patents beyond their initial 20 years by introducing small changes to the substance's composition and then registering a new patent on this essentially unchanged version.

⁹² Bolar provisions streamline the market approval process to facilitate a quicker transition to generic versions of medicines after the expiration of the original patent term (WTO 2002, 44).

⁹³ The period of data exclusivity covers clinical test data to delay the entry into the market of a generic version of the drug in question. This extends the window of profitability in return for the research effort that went into drug discovery in a variety of desirable areas (for example neglected diseases).

⁹⁴ Orphan drug rules prevent other medicines addressing the same condition from getting regulatory approval in a particular national market, thus encouraging the development of treatments for rare diseases. This period of marketing exclusivity usually covers a period of 7-10 years.

⁹⁵ In fact, issuing such a license is in practice discouraged, and only relatively powerful countries manage to successfully make effective use of them.

between health and IP. The negotiations were conducted against the backdrop of mounting concerns about the flexibility of the system even in the countries usually in favour of strong IP rights (t' Hoen 2009). The anthrax scare in the US at the time raised the spectre of a compulsory licence issued by the US for the protection of the health of its population, which “forced all WTO Members to ask themselves how much of a prisoner they wanted to be of their own patent systems” (Ibid., 30). This situation suddenly reversed the usual division of interests. The US found the existing system too rigid to respond to health security crises, which require vast amounts of pharmaceuticals in a very short amount of time – an objective that the licensing and import systems cannot deliver reliably. In this case, the health of its population had to be secured even at the expense of IP standards. This highlights the subversive potential of the biopolitical motivation of “securing” health (Dillon and Lobo-Guerrero 2008; Elbe 2009), which has in this case given rise to an entirely new policy sector surrounding IP and global health.

2.2. Legitimizing IP and ‘TRIPS Plus’ treaties in the name of health

The history of the Doha Declaration on TRIPS and Public Health can thus be read as the introduction of the IP regime to the problematization of governing global life. On the basis of this new connection, a new policy sector emerged at the intersection of IP and global health. The promotion of life and health became a new point of reference for the international IP regime, in what could be interpreted as an international version of somatic ethics influencing international organisations occupied with discussions on IP and health. This reading emphasises the wider implications of a “politics of life” within international organisations, giving context to the finding of a “new moral economy of R&D” (Lezaun and Montgomery 2015, 5) and its potential conflicts with the IP regime. The IP regime is already accommodating this new point of reference, as highlighted by the growing influence of health in the US government’s subsequent attempts of negotiating ‘TRIPS Plus’ bilateral treaties. This process of accommodation can give rise to unexpected tensions within the IP regime – as the discussions of the confrontation with the human right to health and the argument of market failure show (see below).

The US government has been negotiating higher IP and IP enforcement standards nationally and internationally. On the national level, the US attempted to expand the reach of US copyright legislation to the rest of the world by means of

national legislation in the failed SOPA (Stop Online Piracy Act) and PIPA (Protect Intellectual Property Act), which all formed part of the “Campaign to Protect America” (Sell 2008, 6). International standards of IP enforcement have been under negotiation in the controversial Anti-Counterfeiting Trade Agreement (ACTA), Trans-Atlantic Partnership (TPP), and Trans-Atlantic Trade and Investment Partnership (TTIP). While ACTA, for example, does not mention public health, it still applies to pharmaceutical products, and could affect the effective distribution of medicines and the ease of management of public health programmes – by seizing goods in transit “alleged to be infringing “local” patents on their way through European airports” (Abbott 2009, 44; UNAIDS 2011, 34; Roffe and Spennemann 2006). At the same time, ACTA and higher IP enforcement are promoted in order “to protect the health and safety of European consumers”, and critics are reassured that ACTA “contains explicit public health safeguards” (ACG, Andema et al. 2012). Debates about ‘TRIPS-Plus’ standards are thus challenged because of their possible detrimental effects on public health and as a result even these bilateral negotiations are becoming suffused with considerations of the health of populations.

While these bilateral US initiatives are negotiated outside of the WTO, WIPO and WHO structures⁹⁶, further negotiations in these international organisations on the role of IPRs in the field of health also revolve around the compatibility of IP with the priority of global life (see overview of debates at WTO 2015b). WTO Director-General Pascal Lamy found in these debates “a shift in focus from the ‘compatibility’ of trade, intellectual property and health to the more dynamic and constructive ‘coherence’ between them” (WTO 2011). Over the last decade, the WTO, WHO and WIPO have started a process of “consolidating their technical cooperation activities”, resulting for example in a trilateral study on *Promoting Access and Medical Innovation: Intersections between Public Health, Intellectual Property and Trade* (WHO, WIPO, and WTO 2013; other studies look at access to medicines and treatments, innovation and public health, CIPIH 2006; and also provide a general re-assessment of existing international treaties in terms of the way in which they can serve to promote public health, WTO 2002; see also list of available documents at WHO 2015).

⁹⁶ This could be understood as another interesting instance of regime shifting (following Helfer 2004), in which the US is seeking to inscribe its own understanding of IP’s relation to health and security. Negotiations are held in unusual secrecy for trade matters (see description of negotiations in Geist 2010).

The report on *Strengthening Global Financing and Cooperation* (CEWG 2012a) stands out for its particularly critical perspective on the IP system's potential for the promotion of global health goals. The WHO's independent Consultative Expert Working Group (CEWG) on Research and Development suggested alternatives to the existing system, which were greeted as a "breakthrough opportunity" (Stiglitz 2012), but were subsequently severely delayed and watered down in extended and ongoing negotiations at the World Health Assembly (WHA) (Love 2012; WHO 2015; Balasubramaniam 2014; 2013a; 2013b). While the emphasis within most of the other documents remained on the assumption that IP will promote public health within a functioning market through the encouragement of innovation (on this theoretical justification of IP see Merges 2011, 270 ff.), the CEWG report employed the argument of "market failure" in order to highlight the limits of the IP legitimization.

The remainder of this chapter explores specific challenges emerging within this new frame of reference for the legitimization of IP. IP's failure to enable access to medicines has been criticised as a "market failure" in relation to life and health, and has given rise to deliberations of genuine alternatives to the existing IP system. Similarly, the relation of IP to the right to health is being explored, and human rights are considered in negotiations on treaties in WIPO's Intergovernmental Committee (IGC) on *Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*. It is argued that understanding these two arguments as instances of the IP regime acting in a "responsive" way shows how IP as a tactics of governing negotiates tensions between life and the economy: while these strategies push the IP system to its conceptual limits, these challenges are governed and managed by long delays and slow deliberations.

3. Emerging Challenges: Human Rights and 'Market Failure' as Strategies for Intervention in the Name of Life and Health

Some debates within these core institutions at the intersection of life and the global economy are openly questioning IP's legitimacy in the context of global health aims. This section points out that the argument of market failure and the use of human rights are potentially more radical strategic contestations of the exclusionary effects of the IP regime on the international level. The emergence of a new policy area around IP and global health produces tensions between competing priorities in these

negotiations – between life and property. It is argued that these tensions and responses to these arguments within the WTO and WIPO are indicative of a slow process of accommodation within the international IP regime towards demands made in the name of life. This would constitute an opening of this exclusionary apparatus that could have fundamentally “disruptive” potential in the sense of Golder & Fitzpatrick: IP law could “[disrupt] itself through becoming receptive of resistances that constantly challenge its position, its content, its being” (2009, 71). However, the long-term potential of emerging global health strategies of IP law still remains unclear. Lezaun & Montgomery observe that the current emphasis on sharing and openness in the “pharmaceutical commons” may be followed by a return of exclusionary practices capitalizing on “expectation of future enclosures” (2015, 21).

This possibility of a return to exclusionary practices however partly depends on the outcome of debates in the IP system on alternative financing methods and the relation of the IP system to human rights. This section sets out these two challenges to IP’s exclusionary function on the international level, confronting it with the “problem” of life. First, the emerging confrontation between human rights (especially the right to health) and IPRs is still very recent, but tensions between these forms of ‘rights’ are mounting and are yet to be resolved (Helfer and Austin 2011; Cullet 2007; Matthews 2010; Grosheide 2010; Joseph 2011; Hilberg 2015). The negotiation of human rights challenges to IP is explored in the example of ongoing negotiations in WIPO’s IGC on *Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*. Second, the concept of market failure is another example of a challenge to IP’s relation to life: the aim of increasing access to medicines is here coupled with a critique of the economic function of IP (CIPHI 2006; CEWG 2012a; Trouiller et al. 2002; Williams 2012). Both challenges have the potential of contesting the legitimacy of IP, but their interventions are being ‘managed’ by processes of accommodation – in decade-long negotiations in the IGC and through the watering-down of alternatives suggested by the CEWG.

3.1. Introducing Human Rights

IPRs and human rights are two important areas of international law which have only very recently been brought into contact, in fact, “[l]ittle more than a decade ago, few observers acknowledged the existence of such a relationship or viewed it as more than marginally relevant to the important issues and debates in each field” (Helfer and

Austin 2011, 1). An example of this encounter is the recent trilateral study of WHO, WIPO, and WTO, which describes the issue of public health as having “long rightly occupied front rank among priorities for global cooperation”, and states “[t]he right to health is a universal human right, just as the burden of disease is shared by all humanity” (WHO, WIPO, and WTO 2011, 2). This recognises the relevance of the demand for the right to health within the IPRs system, thus creating an opening of the IP system to interventions made from the perspective of *all* humans, not just those directly involved and having a stake in the IP system. However, as this section sets out, this potential has to be re-evaluated with regards to the “ambivalent” potential of human rights to not only contest but also to sustain and entrench existing arrangements, by “conduct[ing] the behaviour and go[ing] to constitute the very identities of those who deploy them” (Golder 2013, 7; Hilberg 2015).

3.1.1. Confronting IP with the ‘positive’ right to health

The right to health has been laid down in the Universal Declaration of Human Rights (1948) under Art. 25, the WHO Constitution (1946), and further defined in the International Covenant on Economic, Social and Cultural Rights (1976) under Art. 12: “The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”. The precise content of the right to health is however not clearly and universally defined, resulting in differing interpretations between for instance different EU states (McHale 2010, 278 f.), and in different positions towards this right held in different international institutions.⁹⁷ In contrast to that, the IP system is very strongly institutionalised, and contains mandatory minimum standards that have to be rendered enforceable within the national legislature of each member state. In these, existing TRIPS flexibilities address health concerns only in a very specific set of circumstances and can only be understood as short-term measures. Beyond these, critics contend that the TRIPS system “undoubtedly elevates IP rights over other potentially conflicting rights” (Joseph 2011, 216).

The confrontation with rights granted to *all* human beings has the potential to disrupt IP’s exclusionary function at the most fundamental level, as demonstrated by the challenge of the Brazilian constitution’s effective guarantee of the right to health

⁹⁷ For one authoritative interpretation issued by a UN body see *General Comment No. 14* (2000) on Art. 12 ICESCR by the Committee on Economic, Social and Cultural Rights (CESCR).

to the IP system (Matthews 2010; Biehl et al. 2009; Reubi 2011). Here, patients invoked the right to health in demands for access to antiretroviral medicines, and in 2001 the Brazilian government became embroiled in a conflict with the US on the issue of compulsory licenses (t' Hoen 2003). This direct confrontation ended with a settlement in the face of widespread protest demonstrations. Similarly, the pharmaceutical industry's attempted legal challenge to the South African government's stance on antiretroviral medicines was dropped in 2000 because of a high-profile media campaign protesting the enforcement of IP (Godoy 2013, 42; Hestermeyer 2007, 11 ff.). These examples highlight the mobilising power of the right to health, and the disruptive potential of this challenge. But an understanding of the role of human rights in the deployment of governmental power can provide a deeper understanding of this encounter, which is often also presented as entirely unproblematic (WHO, WIPO, and WTO 2013). The incremental goal-setting development of the right to health in combination with slow-moving negotiation procedures shows how this confrontation results in slow processes of accommodation rather than upheaval.

Most developments in the area of international human rights law take the form of soft law⁹⁸, which works through voluntary and non-enforceable processes of goal setting. This attribute of progressive fulfilment is especially pronounced in “positive” human rights, which “[require] States to take actions to fulfil the rights therein” – in contrast with “negative rights”, which “[require] only that States refrain from rights violating behaviour” (Joseph 2011, 21).⁹⁹ The right to health and also the general right to property¹⁰⁰ are both positive rights, which are realised in an incremental process – whereas the current IP system consists of mandatory, enforceable standards, which do not share the same flexibility for accommodating new priorities. However, while human rights thus pressure for higher standards and

⁹⁸ The category of soft law “is not of itself ‘law’” but still commands particular power through “recommendations, guidelines, codes of practice or standards”, “signalling the evolution and establishment of guidelines, which may ultimately be converted into legally binding rules” (Shaw 2003, 111). The Helsinki Final Act of 1975 is an example. It is mostly used to flesh out existing standards.

⁹⁹ Economic, social, and cultural rights such as the right to health and the right to property are usually seen as positive rights, whereas political and civil rights are commonly seen as negative rights, however, as Joseph points out, “all human rights entail both positive and negative characteristics” (Joseph 2011, 21).

¹⁰⁰ The TRIPS IP system is a specific version of this contested ‘right to property’, but not coextensive in content, see *General Comment No 17* on Art 15 (1) c ICESCR by the Committee on Economic, Social and Cultural Rights (2006).

can accommodate tensions, their potential effect on the IP system (representing property) is not clearly determined.

3.1.2. The paradoxical potential of rights: Incremental processes of accommodation

The increasingly direct confrontation between the IP system and human rights has so far triggered a number of new developments according to Helfer & Austin's incisive analysis:

“(1) increased attention to the neglected cultural rights of indigenous communities; (2) efforts to identify the adverse consequences of TRIPS and TRIPS Plus treaties for the realization of economic, social, and cultural rights; (3) a growing recognition of the human rights responsibilities of multinational corporations; and (4) attempts by those same corporations to invoke the human right of property as an alternative legal basis for protecting intellectual property.” (Helfer and Austin 2011, 49)

These developments show how comprehensively the human rights argument has been introduced to the IP system – paradoxically both as a means of challenge to TRIPS and TRIPS Plus treaties, but also as a justification for the protection of IP. In this encounter, Helfer & Austin argue that human rights have the potential to “[expose] serious normative deficiencies of expansive intellectual property protection rules from a human rights perspective” (Ibid.). However, this section argues that the question of the “counterhegemonic” potential of human rights (Godoy 2013, 5) has to be contrasted with the “paradoxical” nature of human rights (Brown 2000, 231). This paradox refers to the way in which reliance on human rights captures and conducts the conduct of dissenters to fit essentialised ‘minority’ identities fundamental to human rights norms, and more amenable to the priorities of the (neo)liberal system (Golder 2011; 2013; Odysseos 2010; 2011).

As Odysseos argues, the source of this paradoxical role of human rights becomes more obvious in the “ontogenesis” of the subject of rights, which is a “self-governing subject” akin to the economic subject of neoliberal governmentality (the *homo oeconomicus*), and “contribute[s] positively to the deployment of pastoral power and the governmentalisation of the state” (Odysseos 2010, 755). This

underlying complementarity reveals human rights' contribution to the governing of life and the economy, beyond Foucault's (notoriously conflicted) statements on the role of human rights¹⁰¹: "Foucault's cursory dismissal neglects the ways in which human rights, and their engendering of *homo juridicus*, participate fully in the governmentalisation of the state and the creation and reorganisation of the conditions of freedom, domestically and internationally" (Ibid., 754). In this way, human rights "[become] one of the varied tactics of government" (Ibid., 755), can even be seen to "discipline dissent" (Coleman and Tucker 2011) in the very moment in which it is registered in the language of rights by "[conducting] the behaviour and [...] [constituting] the very identities of those who deploy them" (Golder 2013, 6). Odysseos (2011) shows this gradual process at work in resistance campaigns, in which reliance on human rights and court procedures leads to the increasing adoption of essentialised modes of subjectification.

The realisation of this underlying complementarity of the subject of rights and the economic subject, and human rights' disciplining effect on dissent sheds light on human rights' supportive potential to governmentality's priorities – and undermines the notion of their counterhegemonic potential. Human rights' potential challenge to the IP system can thus be recast as relative to their promotion of the priorities of governmentality. As argued above, the increasing use of the right to health within IP policy discourse has the potential to challenge IP's relation to life by introducing a wider range of perspectives to the exclusionary apparatus of IP. This potential however now appears tempered by human rights' constitutive relation to the new art of governing. The right to health's challenge to IP is thus less radical when the "disciplining" effects of the procedures involved in this mode of contestation are taken into account. These effects can be traced for example longstanding negotiations in WIPO's IGC on *Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*.

WIPO's IGC seeks to formulate international agreements on IP's treatment of genetic resources, traditional knowledge, and folklore as part of WIPO's ambitious development agenda (May 2006; Muzaka 2013). This resulted in a direct confrontation between the fundamentally pro-IP body WIPO and its UN human rights

¹⁰¹ As pointed out in chapter III, Foucault famously found human rights to be "mask" of power relations (Foucault 1977, 222). He later argued for the potential of human rights for confronting governments on the floor of the UN in 1981 (see Foucault 2000, 474; Keenan 2010; Patton 2005; Whyte 2012).

obligations. Years of protracted negotiations even resulted in debates about a fundamental incompatibility between development and IP (Saez 2014c). The unfolding impasse in these negotiations highlights the profound nature of human rights' challenge to the IP system, and the sheer magnitude of problems encountered by the relatively rigid IP system's attempt to accommodate human rights demands. It, however, also contrasts this potential power of rights with the "disciplining" effect of participation in these negotiations.

Most strikingly, this relatively open negotiation of the usually specialist policy area of IP law allows a great variety of different actors to participate. An even wider variety of actors can register comments and suggestions on already negotiated texts, and there is a fund available for the support of NGOs participating in the consultation (WIPO 2012a). This is a radical opening of the IP apparatus towards a variety of new perspectives – those of potentially *all* humans. However, this opening also remains limited as all parties technically are only classed as "observers", and the actual extent of the indigenous rights under discussion is still unclear, as the UN *Declaration on the Rights of Indigenous Peoples* (2007) has not been endorsed by a number of countries with significant indigenous communities, such as "Australia, Canada, New Zealand, and the United States" (Helfer and Austin 2011, 51).

Aside from understanding these actual negotiations as the result of a successful challenge in the name of minority rights, the greatest potential for contestation in these negotiations has derived from giving indigenous communities the opportunity to register their dissatisfaction with the present system. Thus the representatives of indigenous communities walked out of debates held in the Committee on Genetic Resources in 2012 in protest of their status as mere "observers" and issued a statement complaining of the limited way in which their suggestions had been included in the texts thus far (Saez 2012a). However, the next day a draft text of the agreement on genetic resources was still agreed after the communities had rejoined the negotiation (Saez 2012b). Nevertheless, through involvement in the process they had been able to protest their limited input on the final text, which still remains a highly contested work in progress. The 2014 WIPO General Assembly could not agree on a schedule for further negotiations in 2015, so that the decade-long process is currently on hold.

This instance of protestation and subsequent re-negotiation however also shows the palpable "disciplining" effect of these negotiations on indigenous

communities' resistance to the existing IP system. Similarly to Odysseos' analysis, they are becoming "subjects in the process of being governmentalized" through their reliance on rights guaranteed by the system, revealing the function of "law as a tactic of government" (2011, 450). The participation in the IGC led to a debate about the future of IP in a forum that accepts the premise of the need for IP in general. As this challenge is being 'managed' by the IP system, indigenous communities and other participants are negotiating an agreement on access and benefit sharing that questions only the modalities of this premise, not the system as a whole. While they are thus afforded the opportunity to register some dissatisfaction, their dissent is "conducted" and governed in a manner that does no longer radically challenge the general IP system in general.

3.2. Diagnosing Market Failure

These processes of accommodation are also apparent in debates challenging the IP system's "market failure" in developing countries. Under the auspices of WHO, the previously mentioned independent CEWG's report on *Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination* (CEWG 2012a) argued that a "market failure" questions the accepted legitimization of IPRs in certain geographical and social contexts – with regards to their detrimental effects on access to medicines. IP is usually justified as a necessary trade-off within the existing neoliberal 'free market' system, providing inventors with a financial return on their invention, thus making research and development (R&D) of drugs profitable in the long run. Robert Merges explains that in the "current convention" of IP,

"[t]he traditional utilitarian formulation – the greatest good for the greatest number – is expressed here in terms of rewards. [...] The gains from this scheme, in the form of new works created, are weighed against social losses, typically in the form of the consumer welfare lost when embodiments of this works are sold at prices above the marginal cost of their production" (Merges 2011, 2).

This trade-off, however, posits the existence of a functioning market, in which consumers (such as national health services) are able to pay an increased price for

new medications in the short term, and the availability of newer medication will be beneficial for all in the long term. These foundational assumptions are challenged by the argument of ‘market failure’, which has given rise to extended negotiations as well.

3.2.1. Challenging IP’s market failure in Global Health

The concept of ‘market failure’ was introduced to critiques of IP’s relation to life over the last ten years, in a process that has encountered delays and setbacks throughout. An earlier *Commission on Intellectual Property Rights, Innovation and Public Health* (CIPRH) paved the way for the CEWG’s report by clearly setting out the uneven distribution of the global disease burden, and specifically questioning the potential of IPRs in addressing this issue:

“Too few R&D resources are directed to the health needs of developing countries. In the private sector, companies do not have the incentive to devote adequate resources to develop products specifically adapted to the needs of developing countries, because profitability is mainly to be found in rich country markets. The great majority of health research funded by the public sector, takes place in developed countries, and its priorities principally reflect their own disease burden, resource position and social and economic circumstances.” (CIPRH 2006, 172)

Instead, CIPRH argued that as “a prerequisite for access”, “appropriate treatments should be available for diseases and conditions that disproportionately affect developing countries” (Ibid., 171). This may be seen as stating the obvious – however, in the area of IP this statement made under the auspices of a major international organisation constituted a breakthrough, reflecting the shifting frame of reference for IP policy towards “pro-access regimes” (Williams 2012, S129; Rushton and Williams 2012; Lezaun and Montgomery 2015).

Instructed to “deepen the analysis” after developing countries rejected an earlier EWG’s (Expert Working Group) report on financing and R&D (CEWG 2012a, 19), the CEWG picked up the theme of inequality and exclusion introduced by CIPRH and declared a “market failure” where it comes to providing functioning financing

models for R&D in developing countries (Ibid., 24–25). An example for such market failures is the “low level of investment in R&D on antibiotics” and vaccines (Ibid., 24), which is already becoming a global health problem as rates of resistant bacterial strains are increasing. This example shows that the market does not always tend to the most pressing health issues globally (and nationally). The declaration of this fact within an international dialogue on the future role of IP in global health policies poses a major challenge to its accepted role in a neoliberal economy.

The notion of market failure generally addresses an economic situation in which a market operates inefficiently. This common economic concept is used in economic theory in a broad range of ways – but in the WHO’s statements it is used with the express intention of addressing IP’s failure with regards to the health of the global population. However, recent WHO statements show that at times this argument is also taken on in defence of the IP system. Statements on the industry’s failure to develop an Ebola vaccine before the outbreak in 2014 stress that “market failure, not IP, [is] the issue in Ebola treatment shortage” (Saez 2014b). This statement seeks to dispel concerns raised about existing patents on an isolated genetic strain of the Ebola virus, for example on “the isolated human Ebola (hEbola) viruses denoted as Bundibugyo (EboBun)” (Saez 2014a).¹⁰² Williams argues that the presence of pro-access actors “has given the IPR/trade regime an opportunity to reconsolidate, and helped offer it new legitimacy after a period of sustained attacks with regard to its negative impact on drug access” (Williams 2012, S129). This period of “reconsolidation” in the face of substantial challenges to IP’s legitimacy can be interpreted as a part of a process of accommodation taking place at the intersection of life and the economy.

3.2.2. Exploring alternatives to IP

In the face of a failed market, the CEWG report explores radical alternatives to the IP system in order to finance and promote research. One suggestion calls for overt public involvement in the formulation of new priorities for R&D in a “global framework on research and development” guiding research towards health concerns of developing countries. The report also introduces a classification of diseases that directly connects

¹⁰² Patent Application No. CA2741523A1 (<http://www.google.com/patents/CA2741523A1?cl=en> accessed 22.10.2014). This patent shows that global health’s relation to IPRs always also includes the issue of the treatment of genetic information.

disease prevalence with economic circumstances. In contrast with IP's recognition of orphan (i.e. rare in overall terms) or neglected diseases (mostly neglected tropical diseases, which are prevalent in developing countries), the report introduces Type I, II and III diseases:

“Type I diseases are incident in both rich and poor countries, with large numbers of vulnerable populations in each. Type II diseases are incident in both rich and poor countries, but with a substantial proportion of cases in poor countries. Type III diseases are those that are overwhelmingly or exclusively incident in developing countries.”
(CEWG 2012a, 18, Footnote 2)¹⁰³

This classification is an intervention seeking to establish a point of reference that supports findings of market failure. Based on this system, the report recommends for example the removal of orphan drug rules and extensions of data exclusivity, as “there was no evidence that data exclusivity materially contributes to innovation related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases” (Ibid., 54). This would fundamentally alter the system of accepted IP flexibilities set out in the Doha Declaration on TRIPS and public health, making redundant two of the three main measures of IP management in the context of health.

Furthermore, the CEWG report seeks to “[delink] the costs of R&D from production prices” (Ibid., 19 and 53) by suggesting a system of public prizes for fulfilling certain research aims. The explicit aim is “to replace the current [IP] model with a government-supported prize fund”, as

“[w]ith a prize system, innovators are rewarded for new knowledge, but they do not retain a monopoly on its use. That way, the power of competitive markets can ensure that, once a drug is developed, it is made available at the lowest possible price – not at an inflated monopoly price” (Stiglitz 2012).

¹⁰³ Both the CIPIH and CEWG report use the Type I, II and III categories (see t’ Hoen 2009, 83).

However, these more radical recommendations rely greatly on the availability of alternative sources for sustainable funding for R&D efforts according to new priorities (CEWG 2012a, 63). Under consideration are “the proposal of a new indirect tax, voluntary contributions from businesses and consumers, taxation of repatriated pharmaceutical industry profits, and new donor funds for health research and development” (Ibid., 20, table 1.1).

Subsequent negotiations in the WHA significantly diluted the CEWG’s suggestions and halted further progress in this direction at least until 2016 (CEWG 2012b; Kiddell, Iversen, and Gopinathan 2013).¹⁰⁴ In this regard, the lengthy process going back to the CIPIH report (2003) can be interpreted as another example of a process of accommodation in protracted debates in organisations that are generally in favour of IP’s continued existence. The persistent obstacles to implementation of recommendations and attempts at re-negotiation in the WHA are another indicator. Beyond that, these debates show how the IP system faces critique from two sides in this case – in terms of its relation to health and in economic terms. But Williams points out that the pro-access regime has so far “failed to challenge the underlying economic rationale for strict and global drug patents” (2012, S129). The market failure argument creates only a regional exception to the usual IP regime, and does not aim to overturn the entire system.

But the argument of market failure still constitutes an overt intervention against IP’s exclusionary function that in certain circumstances seeks to supplant the market’s determination of the direction of research with an officially formulated agenda. The report proposes to set research targets centrally, as an act of official intervention that counteracts the failure of the market. This strategy is reminiscent of a “biopolitics from above” (Raman and Tutton, 2010, 722), instead of representing a more “capillary” diffusion of biopower. The alternative system of disease classification diffuses power in a more capillary manner, enabling decisions on the applicability of IP rules at diverse sites without recourse to a central decision-making body. The increasing involvement of PPPs and PDPs in global health programmes also contributes to the diffusion of biopower. IP’s relation to these different elements of a “new moral economy of R&D” (Lezaun and Montgomery 2015, 5) can thus be

¹⁰⁴ Comments made by Médecins Sans Frontières in 2013 still deplore the lack of progress with regards to the main recommendations, for example a global R&D framework (Médecins Sans Frontières 2013). However, some preliminary steps have been agreed on at the 67th WHA in 2014 (DNDi 2014).

understood as a complex process of accommodation to an ethics of a new policy sector. Here, the IP regime responds to tensions tactically. While concessions towards failed markets certainly do not extend to an instant threat to the entire IP system, this responsive management of critique could give rise to a situation in which IP law begins to “[disrupt] itself through becoming receptive of resistances that constantly challenge its position, its content, its being” (Golder and Fitzpatrick 2009, 71). The exploration of alternatives to the current IP system, even in limited circumstances, could mark a starting point for new challenges.

Conclusion

The international IP regime still remains exclusionary, especially with regards to attempts at establishing a connection between sources of genetic materials and their further use by industry. Here, IP acts as a very effective and absolute regime for exclusion of participation towards developing countries. However, within an emerging policy area of IP and global health, the role of IPRs is undergoing change. Beginning with the Doha Declaration on TRIPS and Public Health, the connection between IP and global health agendas has given rise to new strategic uses of IP in business models of PPPs and PDPs. A “paradigm shift” (Morin 2014) towards openness is beginning to challenge IP’s legitimacy as a mechanism for promoting research and development of medicines that respond to the health needs of developing countries. These debates on IP and global health are notable because they occur at the core of the IP system, unlike the entirely separate CBD and Nagoya Protocol negotiations. Here, some arguments begin to successfully challenge IP’s exclusion of large parts of the world’s population within international organisations usually predominantly concerned with the protection of IP. Market failure and the right to health both question IP’s legitimacy on a fundamental level by promoting the inclusion of a wider range of perspectives. However, a closer analysis of the actual processes of contestation shows that this disruptive potential is being ‘managed’ by extended negotiations, limited concessions, and the subject of human rights’ active contribution to the fulfilment of neoliberal priorities. In these processes of accommodation, the IP regime contributes to the governing of tensions between life and the economy.

Chapter VII Conclusion

The informational-genetic conception of life gives rise to value within a neoliberal economy – but it also intensifies the problematization of the governing of life. This thesis argued that the resulting tensions could be better understood from an analytic perspective that can grasp the wider social influence of the notion of the genetic code, which gave rise to a new system of truth over human existence, inscribed on the molecular level of the body – and which opened up the body to interventions on the molecular level. The analysis of IP's encounter with a genetic *dispositif* was conducted on three different levels, reflecting a confrontation with the constituent elements of biopower: truth, the subject, and power exercised in the name of life (Rabinow and Rose 2006, 212). In this way, the analysis of IP's treatment of genetic knowledge over life moved beyond previous critiques of the 'commodification' of life by means of IP. Instead of placing overwhelming emphasis on the determination of social relations by economic exchange processes, this analysis can account for a wider range of incentives and responsibilities for participation in the creation of knowledge.

An adapted understanding of the role of law in a governmental system highlighted IP law's contribution to the governing of life in an otherwise perplexing series of judgements on the definition of DNA and in strategic uses of IP ensuring open access to knowledge in a new somatic ethics. It argued that IP law is instrumental in setting up and ensuring the functioning of the market, but also begins to respond tactically to resistances created by the pervasive influence of the genetic *dispositif*. The increasing significance of the intersection between genetic conceptions of life and the IP regime intensified these tensions. An analysis of these tensions highlighted IP's role in establishing control over knowledge for the purpose of participation in the bioeconomy, and its role in the normalisation of knowledge.

In this reading, two trajectories of challenge were identified as significant sites of IP's responsive engagement with exteriority (Golder and Fitzpatrick 2009, 56): the question of participation in the bioeconomy, and tensions surrounding the normalisation of knowledge. These were explored as unfolding contestations over truth discourses over life, responses to demands made by "genetic" subjects relating

to control over genetic truth, and in new strategic interventions challenging IP's relation to life. The analysis of these trajectories highlighted the particular processes of development within a "governmental" rationality, confronted with changing conceptions of life. This contributed to an understanding of governmentality by stressing the role of law as a tactics of the government of life, to an understanding of biopolitics by underlining adjustments to a rise of a new genetic and informational conception of life, and to the study of international relations by showing that international legal frameworks and institutions are integral to emerging key areas of political contestation based on the pursuit of life and health.

1. Broadening the analysis on contestations of IP

The analysis focused on two trajectories of challenges that were not understood adequately in an overwhelming emphasis on 'commodification': the role of IP as a regime that excludes participation in the bioeconomy, and the role of IP in establishing control over a normalised version of knowledge over life. This perspective illuminated otherwise contradictory recent developments affecting the patentability of 'life', emerging strategic uses of IP by subjects that are not primarily motivated by economic incentives, and interventions that challenge rules for access to the bioeconomy within a national and an international context. Incentives for participation in research can for example be understood with reference to a "new somatic ethics" of the self (N. Rose 2008a), containing new rights and responsibilities that are formed on the basis of genetic truth. The analysis of new modes of subjectification showed how IP contributes to the management of their participation in biobanks and personal genomics collections by enabling the derivation of economic value from voluntary donations given to support "research", while also at the same time preventing any further influence on the use of these donations. This highlights how IP operates tactically alongside an ethics that incites the individual to voluntarily contribute to research – in which IP then control the further economic and scientific use of the collected information.

Understanding contestations around IPRs from this perspective can also contextualise relatively surprising developments such as the *Myriad* decision, which introduced an informational definition of genetic sequences into IP law, but in effect reduced its patentability. This came as a shock to the pharmaceutical industry and was the result of a protracted struggle over the 'nature' of genetic sequences in the lower

courts. Instead of focusing on the paradox of diminishing commodification, this perspective can link this change to a broader problematization of life for the purpose of governing. A governmental analysis emphasises the growing importance of knowledge over the natural processes of 'life' for the determination of appropriate strategies promoting the life and welfare of the population. This thesis stressed that the relevance of knowledge over life was intensified by the informational-genetic conception of life, which links knowledge of the individual and of population. The genetic dispositif contains a particularly efficient code for knowledge of "the nature of things" (Foucault 2008, 19). Chapters III and IV argued that an understanding of the pervasive influence of the genetic dispositif can explain the normalisation of informational-genetic truth over life within IP law, even at the expense of the patentability of some forms of genetic sequences.

These questions of access to and control over knowledge were traced in an industrial and policy sector that connects the international and national level. On the international level of IP law, the Doha Declaration on TRIPS and Public Health marked the emergence of new "pro-access regimes" (Williams 2012) and a "new moral economy of R&D" (Lezaun and Montgomery 2015). Since then, IP law also became embroiled in a process of accommodation between its economic role and its centrality to questions of life and health, giving rise to many high-level reports, legal summaries, and instructional workshops. These gave rise to arguments of market failure and the right to health's connection to IP, which have the potential to fundamentally challenge the IP system's economic legitimization. The analysis showed how the IP regime responds tactically to these challenges in a process of accommodation. This process however engrains a new frame of reference in which genuine alternatives to the existing IP system can be explored.

2. The governmentalisation of IP law: Contributions and limitations

The analysis showed how the function of IP law undergoes change as its relation to life becomes a new point of reference. This reading contributes to governmentality studies in international relations, which has thus far neglected to study the role of intellectual property at the intersection of life and the economy. It also introduces the methods of critical legal studies to the discipline of international relations, affecting the way in which law is studied here. The focus on law in this study deliberately directs attention to the foundational role of law, governing for the market through the

creation of predictable objects for exchange. This role is being challenged by IP's relation to genetic conceptions of life, which for example complicates the predictability of underlying truth discourses of life. In this, the analysis also adds to a political economy of IP by investigating the connection between the juridical and the economic sector, drawing attention to law's different contributions to the maintenance of market parameters.

This perspective expands the purview of objects and subjects of government. By addressing the "genetic" subject's conduct of conduct based on a molecular vision of life, this thesis expands the analysis of processes of governing to include more diffuse exercises of power in a new "biopolitics from below" (Raman and Tutton 2010, 722). Similarly, within the emerging policy sector of IP and global health, PPPs and PDPs are also exerting power that "governs" the use of knowledge for the purposes of improving the life and health of populations. These new strategic uses of IP have been neglected by previous studies of IP as an international regime enabling biopiracy. By conceiving of IP's role here as one of "governing", this analysis emphasises ongoing contestations and developments within the regime, instead of understanding IP as global (exclusionary) biopower. Demands for participation and the re-inscription of processes of exclusion can in this context be read as parts of an ongoing governmental process of accommodation.

The concept of biopower can open up otherwise confusing and conflicting developments by directing the focus of analysis away from previously well-exercised sites of inquiry. Instead, this thesis captures the complexity of IP's relation to life by concentrating on the role of subjects, the construction of truth, and new strategic aims for the use of IP. This analytical contribution reveals IP's part in the governing of life through determining access and assigning control over knowledge, and lays the foundation for further empirical research and normative critiques. It specifically enables greater attention to processes of exclusion in a legal regime that connects international standards with national legislation in a unique way. It also facilitates new normative critiques of exclusionary processes in the otherwise pro-access and pro-sharing projects of citizens' science and research projects claiming to "empower" patients and citizens. Furthermore, IP's contribution to the construction of a predictable account of human life also demands more thorough engagement. Using the notion of a confrontation with biopower enables a different approach to these

issues, going beyond the usual focus on “bioethics” (for an overview of bioethics see Dickenson 2012).

However, the analytical power of understanding IP as a tactics of government also has limits. As already pointed out at the beginning of this thesis, the central claim of this study is not that the entire IP regime is undergoing drastic change. This study rather sought to examine otherwise inexplicable contradictory developments within IP’s application to notions of life. The IP regime undoubtedly still remains a very effective apparatus that ensures the patentability of genetic sequences for the benefit of the biotech industry, as Rosenow for example points out (Rosenow 2012). Also, analyses of tensions within the international sphere of IP law cannot take into account the national variants of this IP system. Further empirical study could investigate different regional approaches to access and control.

Similarly, focusing on the changing role of law within a governmental rationality diverts attention from the continuing function of law as an expression of sovereign power, and as a disciplinary tool. As Foucault pointed out, these three modes of power exercise continue to coexist within a governmental rationality (Foucault 2007, 8; Elbe 2009, 64 ff.). Further studies of developments within the international IP regime could trace IP’s involvement in sovereign, disciplinary, and biopolitical power exercises.

Finally, recent critiques of governmentality studies within international relations also highlighted the danger of over-emphasising the extension of international (neo)liberalism (Selby 2007; Chandler 2010, see also discussion in chapter III). This thesis focused on very specific debates within core institutions of the neoliberal international economic order, and on debates conducted within undeniably neoliberal countries such as the US. However, these findings cannot be transposed into statements on a global condition. “Genetic” citizens can only exercise their rights and fulfil their obligations within a very specific economic and cultural context. Other social and economic contexts will not generate the same engagement with the IP regime, as Godoy’s investigation of human rights campaigns against IP in South America discovered (Godoy 2013). Tensions analysed within this thesis thus must be understood as relatively recent and also reflective of specific institutional debates on the international level. The emergence of IP and global health as a new policy sector within certain international organisations is thus a truly international issue, which needs conceptual attention. IP’s confrontation with life, however, is an

issue that connects the national and international level of IP law due to the wide minimum standards of patentability guaranteed in TRIPS.

3. The tactical roles of IP: A regime for exclusion and for the normalisation of knowledge

The analysis of IP's contributions to the governing of life showed that beyond the commodification of 'life' by means of IP, this regime also fulfils a number of other important functions. IP determines the limits to participation in the bioeconomy and it normalises certain types of knowledge at the expense of others. These roles are revealed as they are coming under pressure in their encounter with biopower. Here, even genuine alternatives to the IP system are being deliberated in some cases. For example, the most common legitimization of IPRs as an important tool for encouraging and rewarding expenses of research and development has been challenged in interventions that explored alternatives to IP such as prize funds and suggested an official list of priorities for research rewarded by money raised in form of taxation (CEWG 2012a). This challenge has been countered in campaigns by the pharmaceutical industry emphasising the costs of producing new medicines, linking this cost to the aim of furthering life and health. This marks the emergence of a new frame of reference, which is being taken on not only by developing countries and patients, but also by the industry and pro-IP institutions. Two trajectories are running through interventions made by industry, institutions, PPPs, PDPs, MRCs, and patients: the contestation of limits to participation and the increased use of IP for the purpose of exercising control over knowledge in order to improve access for researchers and exert control over research agendas. These trajectories are connecting a new somatic responsibility of contributing to research, and a new emphasis on sharing and openness.

3.1. The problem of 'access' – IP as a regime of exclusion

One focus of critique emerging around IP is the question of access to medicines. On the international level this issue is mostly explored in the context of developing countries. New strategic uses of IP within these contexts operate through regional exemptions granted voluntarily by the pharmaceutical industry. These voluntary licenses appear less self-effacingly generous if they are understood in combination with the argument of 'market failure', which critiques the absence of legitimating

conditions for the IP regime's usual function of deriving profit for the purpose of financing research. This argument contains a strong normative critique, which can give rise to widespread condemnations of the IP regime's exclusionary effects. At the same time, the pharmaceutical industry does not derive meaningful profits from a failed market. This confluence of strong critique and absence of profits can make the negotiation of voluntary licenses for failed markets more likely. Especially where it comes to medicines for conditions such as HIV/AIDS, 'failed markets' strongly challenge the legitimacy of IP monopolies. In response to the very stark exclusionary function of IP in this case, the Medicines Patent Pool successfully negotiated a range of voluntary licenses. These regional exemptions however fail to challenge the overall legitimacy of IP, and rather constitute a part of a process of accommodation towards priorities of global health.

This role of IPRs is mirrored within other geographical and economic contexts as well, where their exclusionary character is also becoming increasingly contested from the perspective of life and health – yet this challenge is less effective due to the absence of 'market failure'. The prevention of easy access to their BRCA1 and 2 breast cancer gene testing kit was one of the factors that led to the long running lawsuit against Myriad Genetics in *Assoc. for Molecular Pathology v. Myriad* (2013). Very high prices and a very strong enforcement policy prevented scientists from disclosing test results to patients in certain situations¹⁰⁵ and from scientists and patients accessing other laboratories conducting similar tests (which were then closed down after warnings issued by Myriad). This exclusionary function of IPRs – which is the original function of a monopoly – comes under pressure from new modes of subjectification engendered by a somatic ethics placing emphasis on responsible conduct of the individual in terms of health. As individuals (and governments) are turning to analyses of their genomes in order to determine their personal risks, genome scans are becoming part of the health-conscious repertoire of the entrepreneurial autonomous subject of neoliberal governmentality. In some cases, IPRs are standing in the way of broad availability of these tests, while in others, IPRs function as a dividing line between the services offered to the individual (such as gene scans, determination of genetic risks, and in some cases also explanation of results to better "know" yourself) and the services then provided by the business to other

¹⁰⁵ This occurred for example when they conducted 'research' under the research exception granted in the licensing process – this does not allow them to 'treat' patients.

businesses: licensing out the use of the aggregate dataset for use by commercial research.

Here, IPRs operate as a regime of exclusion, demarcating the area of influence of individuals (donors/patients/customers) from that of experts and business. The sphere of participation by individuals is thus structured as one of mostly customers, which need to be giving informed consent and then possibly receive instruction by an expert based on their results extending to the formation of new norms of conduct. Within the sphere of business, in contrast, IPRs turn this information into a commodity that can be circulated in the bioeconomy. Control over the use of this information rests with the business, not the customer, who is only involved in a yes/no decision of consent to the general use of their data.

In contrast to this exclusion from the sphere of business, examples of patients as holders of IP on their ‘own’ genetic condition have shown that this control was exercised for different priorities than that of economic gain – showing that the question of access and participation has implications beyond this economic function. Here, demands for access became the actual motivation for using IP, giving patients control over research and the accessibility of research results. Medical research charities have been most influential in translating these interests in viable research strategies with specific health priorities, relying on the economic function of IP as part of their business model. This reliance on IPRs shows that similar to the argument of ‘market failure’, these biopolitical challenges are not de-legitimising IP, but rather only address the issues of access and control over research. They are thus part of a process of accommodation of the IP system to priorities of life and health, in which the IP law’s response to challenges in the name of life brings about the governmentalisation of law without actually abolishing IP. Within this unfolding process, IP continues to fulfil several functions, which makes it particularly resilient towards challenges by active patients.

3.2. An economic ‘truth’ – IP as a tool for the normalisation of knowledge

One important function of IP within a governmental economy is its contribution to a normalisation of knowledge – rewarding research framed as part of certain scientific paradigms while side-lining others. This role of normalisation remains important even in the face of changing research paradigms. IP’s changing understanding of ‘life’ shows how the genetic sequence went from a special chemical molecule to an

informational entity, and brought about changes in the patentability of genetic sequences in the process. A governmental reading can highlight how the episteme of ‘information’ became central to an ever-increasing integration of different sectors of governing and deriving value from life – making an informational understanding of genetic sequences more amenable for use across the governmental apparatus. IP’s previous understanding of genetic sequences as primarily chemical molecules had been easily integrated into the IP apparatus, where information as such is not patentable. But the epistemic shift towards information proved more influential, and created problems for the IP regime as a result.

The Myriad decision normalised genetic sequences as genetic-informational entities within IP jurisdiction, even at the expense of patentability of some forms of sequences. However, this step still stands in striking contrast to current influential scientific understandings of ‘life’ within the life sciences. Here, a turn away from the centrality of the genetic code is taking place, moving towards accounts emphasising complexity and interaction with the environment. Interestingly, a closer look at the changing jurisdiction on the ‘truth’ of life shows that this turn towards complexity has not been acknowledged or discussed, even though these fields of research date back to the foundational time of molecular biology. In this field, the ‘central dogma’ of genetic determinism marginalised all other conceptions of ‘life’ for most of the twentieth century – becoming influential throughout society and within cultural imagination at the same time. The IP system continues to prioritise this genetic determinist vision of life, and thus contributes to the maintenance of the ‘genetic *dispositif*’. This *dispositif* provides predictable knowledge that disciplines the individual (see Rouvroy 2008), informs biopolitical strategies on the population level, and is easily integrated within the bioeconomy due to its informational character. IP’s role in the normalisation of this predictable form of truth over life thus tactically marginalises other more complex knowledges of life, which have thus far not been able to compete with this central ‘economic’ function of the informational-genetic episteme.

4. Private v public – IP on the contested dividing line in governmentality

The range of IP’s functions places contestations around IP’s relation to life and health at the heart of a struggle between the ‘economic’ disposition of things and the well-being of populations – expressed within neoliberal governmentality in adjustments

between the sphere of ‘public policy’ and the ‘private sector’, between “the question of the too much and the too little” of governmental intervention (Foucault 2008, 28). IPRs are, as Sell noted, “private power, public law” (2003), implemented by means of public law, enshrined in public international treaties, but ensuring private rights and representative of private industry interests. The history of the TRIPS agreement as a part of the WTO negotiations shows a strong involvement of industrialised public powers (national governments) representing the interests of their domestic industries, which rely on IP for parts of their business in the pharmaceutical industry and the motion picture and creative industries.

Foucault’s work points out that direct interventions using public power carry a cost where it comes to their ‘economy’, but at times interventions are necessary to put in place the conditions that will ensure the functioning of private businesses within the market. The potential costs of the TRIPS agreement and the WTO became apparent at the protests surrounding subsequent rounds of negotiation in Seattle, and the attempts at rapprochement with developing countries in the Doha round. While there is of course a strong element of sovereign power contained in these international deliberations, the WTO framework also seeks to implement a global market, with certain guarantees in place for an increasingly ‘liberalised’ exchange system. This is a strongly neoliberal project, in which an ‘economic’ calculation of the appropriate amount of direct intervention aims to ensure a very particular ‘freedom’ of exchange amongst private entities. The relation to freedom at the core of this process is built on tensions, as Foucault points out:

“the liberalism we can describe as the art of government formed in the eighteenth century entails at its heart a productive/ destructive relationship [with] freedom”. (Foucault 2008, 64)

Part of the production of ‘freedoms’ thus always entails the destruction of freedom by means of direct governmental intervention. This ‘freedom’ is not an ideal notion of absence of government interference, but rather a very structured condition of relations, in which certain entities can thrive (in this case private businesses and entrepreneurial responsible subjects). The analysis presented in this thesis investigated IP’s changing role as part of these conditions of freedom, turning the emphasis away from the economy as the source of regulation (which would see these

structures as emerging out of the structuring force of capital, in the shape of a superstructure) towards an understanding of these conditions as interventions that make exchanges possible according to a certain rationality (as Foucault states “One must govern for the market, rather than because of the market” - Ibid., 121). This placed legal regimes for the market at the centre of this enquiry, introducing a more nuanced reading of the role of law in Foucault’s work on governmentality.

Relying on Foucault’s analyses of ‘governmentality’ highlighted the way in which tensions within this productive/ destructive relation to freedom in (neo)liberalism are over time also influenced by increasing biopolitical challenges, as the fostering of life and health of populations is becoming more central to governing. This shows how a shifting terrain between private and public sector is central and essential to neoliberal governmentality, as new priorities are necessitating new levels of public intervention – as the example of the CEWG report’s reliance on new taxes, official prize funds, and public guidance of (global) public health research agendas shows. These recommendations have since been delayed and watered down, as they incurred the ‘economic’ critique of liberalism, which “always suspect[s] that one governs too much” (Ibid., 319) – showing how biopolitical challenges are being continually “managed” (Dean 2010, 120) within neoliberal governmentality. The private sector has in the meantime pursued ‘TRIPS Plus’ agreements, using the pharmaceutical and motion pictures industry’s influence to increase the protection and enforcement of IPRs in international agreements made outside the organisations in which the connection between IPRs and notions of life and health is being addressed.

Conclusion

Adjustments of (neo)liberal governmentality accommodating “state-phobia” (Foucault 2008, 187) with instances of direct biopolitical interventions thus give rise to a political sphere in which the neoliberal system adapts to new knowledges and evolves over time. Life became a sphere into which the economy could expand, creating value – but crucially, this expansion was made possible by a series of deliberate changes, not least the turn towards the informational-genetic truth of life promoted by the Rockefeller Foundation (Kay 1993). A governmental perspective reveals that this expansion also has the reverse effect of creating new somatic ethics (N. Rose 2008a) within an emerging political sphere of life and health, which then

can also create challenges to the parameters of the insertion of life within the bioeconomy.

This “reciprocal effect” between the “neoliberalisation” of life and the “vitalisation” of order (Dillon and Reid 2009, 21) highlights how a greater emphasis on the fostering of life and health of populations, disciplining the individual to become more ‘responsible’ of its own health, can pose a challenge to some elements of the neoliberal order – within which the IP regime represents a particularly tenuous compromise made for the encouragement of research and development. Foucault points out that monopolies “must be prevented [...] [f]or freedom of the internal market to exist” (Foucault 2008, 64). This shows that the legitimacy of IP is directly derived from the role they play in supporting research and development, making the deliberation of alternative methods of financing research a potentially serious challenge to their legitimacy. However, in contrast to this reading emphasising the precarious position of IP within the ‘free’ neoliberal economy, an understanding of the continuing roles of IP in the governing of life shows that they may be more central to neoliberal economy than their ‘official’ legitimisation claims.

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